



International Influenza Laboratory Capacity Review

June 2012: Version 3

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Background

Background of the International Influenza Capacity Review Tool

The CDC-APHL International Influenza Laboratory Capacity Review Tool (IILCRT) is a data gathering tool to assess laboratory capabilities and capacities, with an emphasis on influenza diagnostics. The information collected from the tool can be used to identify a laboratory's strengths and challenges. The capacity review with the IILCRT will be conducted in the laboratory to assess a wide variety of laboratory aspects. The tool consists of nine modular sections which include

- Laboratory Contact Information
- General Laboratory
- Specimen Handling, Collection, and Reporting
- Virology Laboratory
- Molecular Biology Laboratory
- Laboratory Safety and Biosafety
- Quality Assurance / Quality Control
- Equipment
- Training

The modular design of the tool allows for each of the sections described above to be administered independently, and/or by multiple persons if teams are completing the review. The person(s) performing the capacity review, have significant experience in virology (specifically influenza), molecular biology, and influenza diagnostics. In addition, the individual(s) performing the capacity review have experience training laboratory staff with the CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization assays.

Laboratory Contact Information

Laboratory Contact Information

1	Name of Laboratory _____ Address _____ _____ Point of Contact _____ Phone _____ FAX _____ Email _____ Alternate Email (yahoo, gmail, etc.) _____
2	Which WHO region is the laboratory located? AFR <input type="checkbox"/> WPR <input type="checkbox"/> AMR <input type="checkbox"/> SEAR <input type="checkbox"/> EUR <input type="checkbox"/> EMR <input type="checkbox"/>
3	Is the laboratory a WHO National Influenza Center (NIC)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Do not Know/not sure
3a	If No, has the laboratory applied to become a NIC? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Do not Know/not sure
4	Which country is this laboratory's WHO Influenza Reference Laboratory located in? _____
5	Which international funding/partner organizations is the laboratory affiliated with (check all that apply)? Pasteur <input type="checkbox"/> CDC <input type="checkbox"/> WHO <input type="checkbox"/> World Bank <input type="checkbox"/> PAHO <input type="checkbox"/> USAID <input type="checkbox"/> PATH Global Health <input type="checkbox"/> Other (please specify) _____
6	Shipping Address (If different from mailing address) _____ _____

Laboratory Contact Information

7	<p>Contact within Ministry of Health</p> <p>Name _____ Phone _____ Email _____</p> <p>Does the contact within the MoH speak English? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, conversational English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, scientific English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, fluent English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> Other spoken languages (please specify)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
8	<p>Laboratory Director</p> <p>Name _____ Phone _____ Email _____</p> <p>Does the Influenza Laboratory Director speak English? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, conversational English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, scientific English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, fluent English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> Other spoken languages (please specify)? _____</p>
9	<p>Laboratory Supervisor</p> <p>Name _____ Phone _____ Email _____</p> <p>Does the Influenza Laboratory Director speak English? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, conversational English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, scientific English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, fluent English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> Other spoken languages (please specify)? _____</p>

Laboratory Contact Information

10	<p>Influenza Laboratory Supervisor (if different from above)</p> <p>Same as Laboratory Supervisor Above <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Name _____</p> <p>Phone _____</p> <p>Email _____</p> <p>Does the Influenza Laboratory Supervisor speak English? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, conversational English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, scientific English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p> If Yes, fluent English <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Other spoken languages (please specify)? _____</p>
11	<p>Evaluator</p> <p>Signature _____</p> <p>Date of visit _____</p>
12	<p>General Comments/Notes:</p>

General Laboratory

General Laboratory

1	<p>What is the laboratory's affiliation/designation?</p> <p> <input type="checkbox"/> Ministry of Health <input type="checkbox"/> University Laboratory <input type="checkbox"/> Other (please specify) _____ <input type="checkbox"/> National Laboratory <input type="checkbox"/> Hospital Laboratory </p>																								
2	<p>What is the primary function of the laboratory? <input type="checkbox"/> Public Health Surveillance <input type="checkbox"/> National Influenza Center <input type="checkbox"/> Research</p> <p> <input type="checkbox"/> Diagnostic/Clinical <input type="checkbox"/> Clinical <input type="checkbox"/> Other (please specify) _____ </p>																								
3	<p>What surveillance activities does the laboratory participate in (check all that apply)?</p> <p> <input type="checkbox"/> Influenza <input type="checkbox"/> HIV <input type="checkbox"/> Respiratory Viruses (Other than Influenza) <input type="checkbox"/> Other (please specify) _____ </p>																								
4	<p>What infectious disease testing services does the laboratory provide (check all the apply)?</p> <p> <input type="checkbox"/> Influenza <input type="checkbox"/> HIV <input type="checkbox"/> Foodborne <input type="checkbox"/> GI <input type="checkbox"/> STD <input type="checkbox"/> TB <input type="checkbox"/> Respiratory Viruses <input type="checkbox"/> Other (please specify) _____ </p>																								
5	<table border="0" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"></td> <td style="text-align: center; width: 12.5%;">M</td> <td style="text-align: center; width: 12.5%;">T</td> <td style="text-align: center; width: 12.5%;">W</td> <td style="text-align: center; width: 12.5%;">Th</td> <td style="text-align: center; width: 12.5%;">F</td> <td style="text-align: center; width: 12.5%;">Sa</td> <td style="text-align: center; width: 12.5%;">Su</td> </tr> <tr> <td>Which days does the laboratory normally operate?</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> </tr> <tr> <td>How many hours per day does the laboratory normally operate?</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> <td style="text-align: center;">—</td> </tr> </table>		M	T	W	Th	F	Sa	Su	Which days does the laboratory normally operate?	—	—	—	—	—	—	—	How many hours per day does the laboratory normally operate?	—	—	—	—	—	—	—
	M	T	W	Th	F	Sa	Su																		
Which days does the laboratory normally operate?	—	—	—	—	—	—	—																		
How many hours per day does the laboratory normally operate?	—	—	—	—	—	—	—																		
6	<p>How many days per year is the laboratory closed for holidays?</p> <p> <input type="checkbox"/> 0-5 days <input type="checkbox"/> 5-10 days <input type="checkbox"/> More than 10 days </p>																								

General Laboratory

7	Are there specific months where the laboratory is closed for significant time due to other activities? <input type="checkbox"/> Yes <input type="checkbox"/> No																											
7a	If Yes, please specify which one(s): _____ _____																											
8	How many influenza laboratory staff are: Full-time _____ Part-time _____																											
9	How many laboratory staff do you have trained to: Full-time Half-time																											
	Perform influenza virology? _____ _____																											
	Perform influenza molecular biology? _____ _____																											
10	Are laboratory staff cross-trained to perform molecular biology and virology? <input type="checkbox"/> Yes, all staff <input type="checkbox"/> Yes, only select staff members <input type="checkbox"/> No <input type="checkbox"/> Don't know/not sure																											
11	Please describe the duties of the influenza laboratory staff including:																											
	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 33%;">Name</th> <th style="width: 33%;">Title</th> <th style="width: 33%;">Duties</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table>	Name	Title	Duties																								
Name	Title	Duties																										

General Laboratory

12	On average, how many hours per week do influenza laboratory staff work on other activities besides influenza testing? _____
13	Does the laboratory perform virus isolation? <input type="checkbox"/> Yes <input type="checkbox"/> No
13a	If no, why? _____
14	Does the laboratory perform PCR? <input type="checkbox"/> Yes <input type="checkbox"/> No
14a	If no, why? _____
15	Approximately how many influenza specimens does the laboratory receive for diagnostic testing per week? _____
16	Does the laboratory perform any influenza testing from non-human specimens? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe: _____

General Laboratory

17	Does the laboratory participate in External Quality Assessment Programs? <input type="checkbox"/> Yes <input type="checkbox"/> No																		
17a	How many panels did your laboratory complete in the past year? _____																		
17b	<table style="width: 100%; border: none;"> <tr> <td style="width: 25%;"></td> <td style="width: 15%; text-align: center;">Date</td> <td style="width: 15%; text-align: center;">Score</td> <td style="width: 45%;"></td> </tr> <tr> <td>If yes, please provide score(s):</td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> <td></td> </tr> <tr> <td></td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> <td></td> </tr> <tr> <td></td> <td style="text-align: center;">_____</td> <td style="text-align: center;">_____</td> <td style="text-align: right;">**Please provide most recent documentation</td> </tr> </table>		Date	Score		If yes, please provide score(s):	_____	_____			_____	_____			_____	_____	**Please provide most recent documentation		
	Date	Score																	
If yes, please provide score(s):	_____	_____																	
	_____	_____																	
	_____	_____	**Please provide most recent documentation																
18	<p>Is there a responsible official for receiving specimens:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 25%;">Time of Day</th> <th style="width: 10%;">Yes</th> <th style="width: 10%;">No</th> <th style="width: 15%;">Don't know/Not sure</th> <th style="width: 20%;">If yes, title of the responsible officer</th> <th style="width: 20%;">If no, who receives specimens?</th> </tr> </thead> <tbody> <tr> <td>During Normal Operating Hours</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>After Normal Operating Hours</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Time of Day	Yes	No	Don't know/Not sure	If yes, title of the responsible officer	If no, who receives specimens?	During Normal Operating Hours						After Normal Operating Hours					
Time of Day	Yes	No	Don't know/Not sure	If yes, title of the responsible officer	If no, who receives specimens?														
During Normal Operating Hours																			
After Normal Operating Hours																			
19	Does the laboratory have security measures in place? <input type="checkbox"/> Yes <input type="checkbox"/> No																		
19a	<p>If yes, what are these measures (check all that apply)?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;"><input type="checkbox"/> Electronic surveillance (cameras)</td> <td style="width: 50%;"><input type="checkbox"/> ID badges</td> </tr> <tr> <td><input type="checkbox"/> Manned surveillance</td> <td><input type="checkbox"/> Require sign-in of visitors</td> </tr> <tr> <td><input type="checkbox"/> Electronic security system</td> <td><input type="checkbox"/> Other (please specify) _____</td> </tr> <tr> <td><input type="checkbox"/> Front door chain locks</td> <td></td> </tr> </table>	<input type="checkbox"/> Electronic surveillance (cameras)	<input type="checkbox"/> ID badges	<input type="checkbox"/> Manned surveillance	<input type="checkbox"/> Require sign-in of visitors	<input type="checkbox"/> Electronic security system	<input type="checkbox"/> Other (please specify) _____	<input type="checkbox"/> Front door chain locks											
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<input type="checkbox"/> Electronic security system	<input type="checkbox"/> Other (please specify) _____																		
<input type="checkbox"/> Front door chain locks																			
20	Does the laboratory have a written biosecurity plan? <input type="checkbox"/> Yes <input type="checkbox"/> No																		
20a	If no, would you be interested in assistance developing one? <input type="checkbox"/> Yes <input type="checkbox"/> No																		

General Laboratory

21	Does the laboratory have biosecurity measures in place (i.e. to prevent internal theft)? <input type="checkbox"/> Yes <input type="checkbox"/> No																				
21a	<p>If yes, what are these biosecurity measures (check all that apply)?</p> <p><input type="checkbox"/> ID badges <input type="checkbox"/> Cameras</p> <p><input type="checkbox"/> Freezer locks <input type="checkbox"/> Restricted access to laboratories (i.e.BSL 3)</p> <p><input type="checkbox"/> Restricted access to buildings <input type="checkbox"/> Other (please specify)_____</p>																				
22	Does the laboratory have facilities that maintain and care for animals? <input type="checkbox"/> Yes <input type="checkbox"/> No																				
22a	<p>If yes, what animals, and what is the purpose of the animals?</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>																				
23	Does the laboratory appear to be structurally sound (no missing windows, doors, etc.)? <input type="checkbox"/> Yes <input type="checkbox"/> No																				
24	<p>Please indicate the condition of the following in the laboratory:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 20%;">Good</th> <th style="width: 20%;">OK</th> <th style="width: 20%;">Bad</th> <th style="width: 20%;">Non-Existing</th> </tr> </thead> <tbody> <tr> <td style="text-align: right;">AC</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: right;">Ventilation</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: right;">Lighting</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Good	OK	Bad	Non-Existing	AC					Ventilation					Lighting				
	Good	OK	Bad	Non-Existing																	
AC																					
Ventilation																					
Lighting																					
25	Does laboratory equipment appear to be placed appropriately given any structural limitations? <input type="checkbox"/> Yes <input type="checkbox"/> No																				

General Laboratory

26	<p>In an average week, please indicate the percentage of availability for the following utilities:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 35%;"></th> <th style="width: 15%; text-align: center;">Less than 10%</th> <th style="width: 15%; text-align: center;">10-50%</th> <th style="width: 15%; text-align: center;">50-99%</th> <th style="width: 15%; text-align: center;">100%</th> </tr> </thead> <tbody> <tr> <td style="text-align: right; padding-right: 5px;">Electricity</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">Water</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>		Less than 10%	10-50%	50-99%	100%	Electricity					Water				
	Less than 10%	10-50%	50-99%	100%												
Electricity																
Water																
26a	<p>Is the available electrical capacity sufficient to power all equipment? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>															
27	<p>Does the laboratory have an emergency generator/power supply? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>															
27a	<p>If yes, do you routinely check its operational status? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>															
28	<p>Are critical equipment (PCR machines, freezers, etc.) connected to UPS battery backups? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>															
28a	<p>If yes, do you routinely check its operational status? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>															
28b	<p>If yes, please indicate voltage capacity:</p> <p><input type="checkbox"/> 220V</p> <p><input type="checkbox"/> 110V</p> <p><input type="checkbox"/> Do not know</p>															
29	<p>Is the laboratory supported by maintenance staff? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>															
29a	<p>If yes, what type of staff (check all that apply): <input type="checkbox"/> Plumber <input type="checkbox"/> Electrician <input type="checkbox"/> Mechanical</p> <p><input type="checkbox"/> Other (please specify) _____</p>															

General Laboratory

Laboratory Response	
30	Has the laboratory obtained information concerning the WHO International Health Regulations? <input type="checkbox"/> Yes <input type="checkbox"/> No
30a	Does your laboratory have contact information for the Ministry of Health's IHR focal point? <input type="checkbox"/> Yes <input type="checkbox"/> No
30b	If yes, what is the contact process? _____
31	Does the laboratory have a crisis plan that can be instituted during an emergency (e.g. national disaster, pandemic)? <input type="checkbox"/> Yes <input type="checkbox"/> No
31a	If no, are you interested in developing one? <input type="checkbox"/> Yes <input type="checkbox"/> No
32	Is there a 24 hour, 7 day emergency contact, in case of critical equipment failure or disease outbreaks? <input type="checkbox"/> Yes <input type="checkbox"/> No
32a	If yes, what is their job title? _____
33	Is the laboratory part of any committee related to public health event management? <input type="checkbox"/> Yes <input type="checkbox"/> No
34	Is the laboratory part of a working group for influenza outbreak investigation? <input type="checkbox"/> Yes <input type="checkbox"/> No
35	Did you participate in any influenza field or outbreak investigations during the past year? <input type="checkbox"/> Yes <input type="checkbox"/> No

Influenza Testing Algorithm

36 Please provide a brief description of the laboratory's algorithm for culturing specimens.

***Please attach a schematic outline of the laboratory's algorithm**

Is the laboratory's algorithm acceptable? Recommendation Acceptable

37 What are the top three parameters for altering the seasonal influenza algorithm?

1. _____

2. _____

3. _____

38 Please provide a brief description of the laboratory's protocol/algorithm for the unsubtypeable influenza A specimens.

***Please attach a schematic outline of the laboratory's algorithm**

Is the laboratory's protocol/algorithm acceptable? Recommendation Acceptable

General Laboratory

39	Does the laboratory have a written plan to address influenza surge capacity activities? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, briefly describe: _____ _____ _____
39a	If no, is the laboratory interested in assistance for developing one? <input type="checkbox"/> Yes <input type="checkbox"/> No
40	General Comments/Notes: _____

Specimen Handling, Collecting, and Reporting

Specimen Handling, Collecting, and Reporting

- 1** Does the laboratory have written procedures for influenza specimen:
- Collection? Yes No Logging? Yes No Shipping? Yes No
- Transport? Yes No Processing? Yes No
- Labeling? Yes No Storage? Yes No
- 1a** What is the laboratory's policy for shipping infectious substances to WHO, NIC, or other reference laboratories? _____
- _____
- Is the laboratory's policy for shipping influenza specimens acceptable? Recommendation Acceptable
- 2** What type of Viral Transport Medium (VTM) is used?
- WHO VTM Universal Transport medium
- Commercial VTM Other VTM (please describe) _____
- 3** What types of influenza specimens does the laboratory accept (check all that apply)?
- Nasopharyngeal swabs Throat swabs
- Nasopharyngeal washes Dual nasopharyngeal swabs/ throat swabs
- Nasopharyngeal aspirates Serum
- Nasal swabs Other (please describe) _____
- 4** Is an influenza like illness or severe acute respiratory infection case definition used in selecting patients for specimen collection? Yes No

Specimen Handling, Collecting, and Reporting

Influenza Specimen Receiving

5 Who sends influenza specimens to your laboratory (check all that apply)?

Sentinel providers

Clinical laboratories

Out reach clinics

Physician offices

Hospital facilities

Other (please describe) _____

6 How are influenza specimens triaged (check all that apply)?

All tested

Subset are tested

Other (please specify) _____

7 Please describe the quality control measures done to make sure the cold chain was maintained. _____

Specimen Handling, Collecting, and Reporting

8 How are influenza specimens stored at the **sentinel surveillance sites**?

Cold Storage	Normal Hours		After Hours
	Y/N	How Long?	How Long?
Refrigeration (2°C to 8°C)			
Freezer (< -20 °C)			
Freezer (-70°C to -80°C)			
Other (please specify)			

Is the storage of influenza specimens at sentinel surveillance sites acceptable? Recommendation Acceptable

8a How are influenza specimens stored **prior to laboratory testing**?

Cold Storage	Normal Hours		After Hours
	Y/N	How Long?	How Long?
Refrigeration (2°C to 8°C)			
Freezer (< -20 °C)			
Freezer (-70°C to -80°C)			
Other (please specify)			

Is the storage of influenza specimens prior to laboratory testing acceptable? Recommendation Acceptable

9 Is there a designated area within influenza for receiving specimens? Yes No

10 Do you encounter the following problems when receiving samples:

	Always	Sometimes	Never
Wrongly packaged?			
Wrong temperature?			
Wrong identification?			
Delay in sample delivery?			

Specimen Handling, Collecting, and Reporting

11	Does the laboratory provide a unique identifier for all influenza specimens? <input type="checkbox"/> Yes <input type="checkbox"/> No
12	Are influenza specimens aliquoted before being frozen? <input type="checkbox"/> Yes <input type="checkbox"/> No
13	Does the laboratory have written criteria for influenza specimen rejection? <input type="checkbox"/> Yes <input type="checkbox"/> No
13a	If yes, please specify: _____ _____
14	<p>What original clinical specimens does the laboratory retain for at least a year (check all that apply):</p> <p><input type="checkbox"/> All specimens <input type="checkbox"/> Specimens testing both positive/negative</p> <p><input type="checkbox"/> Only specimens testing positive <input type="checkbox"/> All inconclusive specimens</p> <p><input type="checkbox"/> Only specimens testing negative</p> <p>14a If influenza specimens cannot be retained, why? _____ _____</p> <p>Is the retention of specimens acceptable? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable</p>

Specimen Handling, Collecting, and Reporting

Influenza Specimen Reporting

15 Please indicate who receives your laboratory's specimen results:

	Reporting Methods				Frequency (e.g. daily, weekly, monthly)	Turn around time from receipt of speci- men (e.g. <24 hrs, 24hrs, 48hrs, 1 week)
	Electronic	Fax	Phone	Other (please specify)		
WHO FluNet						
Ministry of Health						
Specimen Submitter						

Other (please specify): _____

Is the laboratory's reporting acceptable? Recommendation Acceptable

16 Does the laboratory have reliable connectivity to report out results (cell phones, landlines, internet)? Yes No

17 How often are **summary** reports generated?
 Daily Weekly Monthly Other (please specify) _____

Specimen Handling, Collecting, and Reporting

18	Does the laboratory use standardized forms to report results? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>*Please provide a copy of the laboratory's standard reporting form</i>
19	Does the laboratory staff know what the reporting requirements are under the International Health Regulations (IHR)? <input type="checkbox"/> Yes <input type="checkbox"/> No
20 20a	Do test results undergo internal review prior to reporting out? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Sometimes If yes or sometimes, briefly describe the internal review process. _____ _____
21 21a	Is there a written policy for rapid notification of reportable influenza cases? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe: _____ _____

Specimen Handling, Collecting, and Reporting

Influenza Specimen Records	
22	Does your laboratory maintain records of reported results? <input type="checkbox"/> Yes <input type="checkbox"/> No
22a	If yes, how long? _____
23	What methods are used to archive reported results? _____ _____
23a	If archived electronically, how are the records backed up? _____
24	Is there restricted access to archived records? <input type="checkbox"/> Yes <input type="checkbox"/> No
24a	If yes, who has access? _____
Influenza Specimen Shipping	
25	How many times a year are virus isolates or rt-PCR positive specimens sent to WHO (collaborating center or NIC)? _____
25a	Which WHO collaborating center does the laboratory send isolates or RNA positive specimens to? _____ <i>*Please provide additional information regarding specimen shipping in the table at the end of this section.</i>
	Is the laboratory's shipping frequency acceptable? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable

Specimen Handling, Collecting, and Reporting

30	Does the laboratory experience any problems or difficulties with customs? <input type="checkbox"/> Yes <input type="checkbox"/> No
30a	If yes, please explain: _____ _____

Training

31	Is internal training offered for staff on: Specimen collection transport and labeling? <input type="checkbox"/> Yes <input type="checkbox"/> No Specimen receiving? <input type="checkbox"/> Yes <input type="checkbox"/> No Shipping infectious substances? <input type="checkbox"/> Yes <input type="checkbox"/> No
31a	What topics are covered during training (e.g. specimen storage prior to collection, specimen packaging for transport, labeling, logging, processing, storage)? _____ _____ *Please provide additional information in the training table

32	General comments/notes regarding specimens : _____ _____ _____ _____ _____ _____
-----------	--

Specimen Handling, Collecting, and Reporting

Specimen

Please indicate the number of specimens for each of the following and where they were shipped within the past year for your laboratory:

Month	Year	A				B	Unidenti- fied	Other (specify)	To WHOCC in:				
		Pandemic A(H1)	A (not- subtyped)	A(H1)	A(H3)				Australia	Japan	US	UK	China

Virology Laboratory

Virology Laboratory

1 Please indicate what influenza testing methods your **virology** laboratory currently performs.

Virus Type	Current Direct Detection Methods					
	DFA	ELISA	Neutralization	HA	Virus Isolation	Other
Human Influenza A/H1						
Human Influenza A/H3						
Human Influenza B						
2009 AH1N1pdm						
H5 Avian Influenza						
High Pathogenic Avian Influenza						
Low Pathogenic Avian Influenza						
Other Avian Influenza						
Other (please specify): _____						

Virology Laboratory

2 Does the laboratory perform isolation for **viruses other than influenza**?

Virus Type	Virus Isolation	
	Yes	No
Respiratory syncytial virus (RSV)		
Coronavirus		
Adenovirus		
Parainfluenza (HPIV)		
Rhinovirus		
Picornavirus		
Metapneumovirus (MPV)		
Measles		

Other (non-influenza e.g. dengue, rotavirus) please specify: _____

**If your laboratory performs virus isolation, please provide additional information in the table at the end of this section.*

3 Does the laboratory assign strain designations to influenza viruses? Yes No

3a If yes, please describe which nomenclature is used (e.g. WHO criteria): _____

Virology Laboratory

4	<p>If your laboratory is performing immunofluorescence testing please indicate kit and source.</p> <p style="text-align: center;">Kit and Source</p> <p><input type="checkbox"/> DFA _____</p> <p><input type="checkbox"/> IFA _____</p>
5	<p>Does the laboratory perform haemagglutination inhibition testing (HAI)? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>5a If yes, does the laboratory use the WHO reagent kit? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>5b If yes, from which WHO Center? _____</p> <p>5c If yes, what is the laboratory's main source of red blood cells: Animal _____ Vendor / Source _____</p>
6	<p>Is there virology research conducted in the same laboratory as diagnostic testing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<h3>Influenza Virus Culture</h3>	
7	<p>How much experience does the laboratory have performing influenza virus culture? <input type="checkbox"/> < 6 months <input type="checkbox"/> 6 - 12 months <input type="checkbox"/> >12 months</p>

Virology Laboratory

8	<p>Does the laboratory use cell culture, eggs, or both? <input type="checkbox"/> Cell Culture <input type="checkbox"/> Eggs <input type="checkbox"/> Both</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 33%; text-align: center;">Cell Line</th> <th style="width: 33%; text-align: center;">Source</th> <th style="width: 34%; text-align: center;">QC Testing for Mycoplasma sp. performed (Y/N)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </tbody> </table> <p>Does the laboratory perform quality control testing for Mycoplasma on all cell lines? If yes, please check acceptable. <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable</p>	Cell Line	Source	QC Testing for Mycoplasma sp. performed (Y/N)																											
Cell Line	Source	QC Testing for Mycoplasma sp. performed (Y/N)																													
9	<p>Under normal operating conditions, how often are influenza specimens cultured during peak influenza season?</p> <p><input type="checkbox"/> Daily <input type="checkbox"/> Weekly <input type="checkbox"/> Monthly <input type="checkbox"/> Other (please specify) _____</p> <p>Is the frequency of culturing specimens during peak influenza season acceptable? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable</p>																														
10	<p>Approximately what percent of RT-PCR positive influenza specimens are cultured?</p> <p><input type="checkbox"/> Less than 10% <input type="checkbox"/> 10-20% <input type="checkbox"/> 20-30% <input type="checkbox"/> 30-40% <input type="checkbox"/> 40-50% <input type="checkbox"/> Greater than 50%</p>																														
11	<p>What types of vessels are used for cell culture (check all that apply)?</p> <p><input type="checkbox"/> Flasks <input type="checkbox"/> Tubes <input type="checkbox"/> Shell vials <input type="checkbox"/> Other (please specify) _____</p>																														

Virology Laboratory

12	Is there a designated clean room for cell culture? <input type="checkbox"/> Yes <input type="checkbox"/> No
12a	If no, where do you perform cell culture? _____
12b	If no, how do you prevent contamination? _____

Contamination Control

13	Does the virology laboratory have a protocol to monitor contamination? <input type="checkbox"/> Yes <input type="checkbox"/> No
13a	If yes, please describe: _____ _____ _____

14	In the virology laboratory , is there task-specific dedication and separation of: Pipettes <input type="checkbox"/> Yes <input type="checkbox"/> No PPE <input type="checkbox"/> Yes <input type="checkbox"/> No Instrumentation <input type="checkbox"/> Yes <input type="checkbox"/> No Equipment <input type="checkbox"/> Yes <input type="checkbox"/> No Supplies <input type="checkbox"/> Yes <input type="checkbox"/> No Reagents <input type="checkbox"/> Yes <input type="checkbox"/> No
----	---

Virology Laboratory

15	<p>Are there separate Biosafety Cabinets (BSCs) designated for influenza virology:</p> <p>Cell culture <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Virus isolation <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Avian influenza (i.e. H5N1) <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Non-human influenza <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												
16	<p>Does the virology laboratory have a designated shelf or space for:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 30%;">Products</th> <th style="width: 30%;">Freezer (Y/N)</th> <th style="width: 40%;">Refrigerator (Y/N)</th> </tr> </thead> <tbody> <tr> <td>Reagents</td> <td></td> <td></td> </tr> <tr> <td>Controls</td> <td></td> <td style="background-color: #cccccc;"></td> </tr> <tr> <td>Archived influenza specimens</td> <td></td> <td style="background-color: #cccccc;"></td> </tr> </tbody> </table>	Products	Freezer (Y/N)	Refrigerator (Y/N)	Reagents			Controls			Archived influenza specimens		
Products	Freezer (Y/N)	Refrigerator (Y/N)											
Reagents													
Controls													
Archived influenza specimens													
Virology Quality Assurance													
17	<p>Does the laboratory have written quality control virology procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												
17a	<p>Are the procedures updated regularly? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Do not Know/not sure</p>												
18	<p>Does the laboratory quality control all reagents and standards used for virology procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												
19	<p>Are critical reagents stored properly (antibiotics at @ 2°C to 8°C, BCS at -20°C) for virology procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												

Virology Training

20 Is **internal** training offered for **virology** staff on virology methods? Yes No

20a What topics are covered during training (e.g. cell culture)? _____

***Please provide additional information in the training table**

21 General comments/notes regarding **virology**: _____

Virology Laboratory

Virus Isolation

Is the frequency of virus isolation activity acceptable? Recommendation Acceptable

Please estimate the number of strains your laboratory isolated within the past 2 years:

Date (mm/yyyy)	No. of Specimen		No. of strains isolated						
	Collected	Processed	A (not- subtyped)	A(H1)	Pandemic A(H1)	A(H3)	B	Unidentified	Other (specify)

Molecular Biology Laboratory

Molecular Biology Laboratory

1

Please indicate what influenza testing methods your **molecular biology** laboratory currently performs.

Virus Type	Current Direct Detection Methods				
	RT-PCR	Conventional PCR	Antiviral Testing	Rapid Influenza Diagnostic Tests	Other
Human Influenza A/H1					
Human Influenza A/H3					
Human Influenza B					
2009 AH1N1pdm					
H5 Avian Influenza					
High Pathogenic Avian Influenza					
Low Pathogenic Avian Influenza					
Other Avian Influenza					
Other influenza viruses (please specify below): _____					

2

Approximately how many influenza specimens can the laboratory staff process **per week** by **RT-PCR**?

- Less than 5
 5-10
 10-15
 15-20
 Greater than 20
 Other (please specify): _____

Molecular Biology Laboratory

<p>2a</p>	<p>Under normal operating conditions:</p> <p>Is your laboratory able to process all specimens within 1 week of receiving them? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>How many RT-PCR runs can the laboratory execute per day? _____</p> <p>How many specimens can be subtyped per day? _____</p> <p>What percent of your specimens are positive for influenza A? _____</p>
<p>3</p>	<p>If the influenza laboratory is performing Real Time (RT-PCR) and Conventional PCR, which kit(s) and manufacturer are used?</p> <p>_____</p> <p>_____</p> <p>_____</p>
<p>4</p>	<p>Please describe how each diagnostic RT-PCR run is set up (e.g. review SOP and describe plate set up, controls, etc.): _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>*Please provide Standard Operating Procedure for RT-PCR.</p>
<p>5</p>	<p>Does your molecular biology laboratory have a designated area for PCR set up? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>6 6a</p>	<p>Does the laboratory have a uni-directional workflow (pre-amplification to post-amplification) for PCR? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, why? _____</p>

Molecular Biology Laboratory

7	Is there a designated area for handling RNA? <input type="checkbox"/> Yes <input type="checkbox"/> No
8	What method does the laboratory currently use for RNA isolation / purification ? _____
8a	If a kit is employed to purify RNA, please identify which kit and the manufacturer. _____
9	<p>What specific primers and probes are the laboratory using for influenza testing (e.g. source/manufacturer/other)?</p> <p>Seasonal/Novel Influenza _____</p> <p>Avian Influenza _____</p> <p>Other _____</p>
10	Does the laboratory use any system for internal quality control? <input type="checkbox"/> Yes <input type="checkbox"/> No
10a	If yes, please describe: _____ _____
11	Are internal controls included in each test run? <input type="checkbox"/> Yes <input type="checkbox"/> No
11a	If Yes, is the performance of these internal controls recorded and monitored over time? <input type="checkbox"/> Yes <input type="checkbox"/> No
11b	If Yes, is there acceptance / rejection criteria? <input type="checkbox"/> Yes <input type="checkbox"/> No

Molecular Biology Laboratory

12	Does the laboratory have a reliable source for RT-PCR reagents and supplies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12a	If yes please identify the reagents (e.g. superscript, extractions kits, etc) and the sources (e.g. CDC, WHO, Manufacturer, etc.).	
	Reagent	Source
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
	_____	_____
12b	Does the laboratory have difficulty procuring reagents?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12c	If yes, which reagents and why? _____	

Sequencing

13	Does the laboratory perform influenza sequencing? <input type="checkbox"/> Yes <input type="checkbox"/> No	
13a	If yes, where is the sequence data deposited?	
	<input type="checkbox"/> GISAID <input type="checkbox"/> GenBank <input type="checkbox"/> Other (please specify): _____ <input type="checkbox"/> Not reported	
	Does the laboratory use an acceptable method for reporting sequence data? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable	

Molecular Biology Laboratory

<p>14</p> <p>14a</p>	<p>Does the laboratory perform influenza phylogenetic analyses? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, please explain: _____</p>						
<h3>Storage and Contamination Control</h3>							
<p>15</p> <p>15a</p>	<p>Does the molecular biology laboratory have a protocol to monitor contamination? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If Yes, please describe: _____</p>						
<p>16</p>	<p>Is there a designated area for handling post-PCR amplified product? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>						
<p>17</p>	<p>In the molecular biology laboratory, is there task-specific dedication and separation of:</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Pipettes <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td style="width: 50%;">Equipment <input type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> <tr> <td>PPE <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Supplies <input type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> <tr> <td>Instrumentation <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Reagents <input type="checkbox"/> Yes <input type="checkbox"/> No</td> </tr> </table>	Pipettes <input type="checkbox"/> Yes <input type="checkbox"/> No	Equipment <input type="checkbox"/> Yes <input type="checkbox"/> No	PPE <input type="checkbox"/> Yes <input type="checkbox"/> No	Supplies <input type="checkbox"/> Yes <input type="checkbox"/> No	Instrumentation <input type="checkbox"/> Yes <input type="checkbox"/> No	Reagents <input type="checkbox"/> Yes <input type="checkbox"/> No
Pipettes <input type="checkbox"/> Yes <input type="checkbox"/> No	Equipment <input type="checkbox"/> Yes <input type="checkbox"/> No						
PPE <input type="checkbox"/> Yes <input type="checkbox"/> No	Supplies <input type="checkbox"/> Yes <input type="checkbox"/> No						
Instrumentation <input type="checkbox"/> Yes <input type="checkbox"/> No	Reagents <input type="checkbox"/> Yes <input type="checkbox"/> No						
<p>18</p>	<p>Are any of the following dedicated for pre-PCR use only?</p> <p><input type="checkbox"/> Pipettes <input type="checkbox"/> Personal protective equipment (PPE) <input type="checkbox"/> Supplies <input type="checkbox"/> Reagents <input type="checkbox"/> Centrifuges</p> <p><input type="checkbox"/> Other (please specify) _____</p>						

Molecular Biology Laboratory

<p>19</p>	<p>Does the molecular biology laboratory have a designated shelf or space for:</p> <table border="1" data-bbox="254 228 1577 402"> <thead> <tr> <th data-bbox="254 228 674 272">Products</th> <th data-bbox="674 228 1125 272">Freezer (Y/N)</th> <th data-bbox="1125 228 1577 272">Refrigerator (Y/N)</th> </tr> </thead> <tbody> <tr> <td data-bbox="254 272 674 316">Influenza molecular reagents</td> <td data-bbox="674 272 1125 316"></td> <td data-bbox="1125 272 1577 316"></td> </tr> <tr> <td data-bbox="254 316 674 360">Influenza positive control</td> <td data-bbox="674 316 1125 360"></td> <td data-bbox="1125 316 1577 360" style="background-color: #cccccc;"></td> </tr> <tr> <td data-bbox="254 360 674 402">Archived influenza specimens</td> <td data-bbox="674 360 1125 402"></td> <td data-bbox="1125 360 1577 402" style="background-color: #cccccc;"></td> </tr> </tbody> </table>	Products	Freezer (Y/N)	Refrigerator (Y/N)	Influenza molecular reagents			Influenza positive control			Archived influenza specimens		
Products	Freezer (Y/N)	Refrigerator (Y/N)											
Influenza molecular reagents													
Influenza positive control													
Archived influenza specimens													
<p>20</p> <p>20a</p>	<p>Are critical reagents (i.e. enzymes) stored in frost free freezers? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, is the automatic defrost disabled? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												
<h3>Molecular Quality Assurance</h3>													
<p>21</p> <p>21a</p>	<p>Does the laboratory have written quality control molecular procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, are the procedures updated regularly? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												
<p>22</p>	<p>Does the laboratory quality control all reagents and standards used for molecular procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>												
<p>23</p>	<p>Are critical reagents stored properly (enzymes @ -20°C, buffers @ 2°C to 8°C, etc.) for molecular procedures?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>												

Molecular Biology Training

24 Is **internal** training offered for **molecular biology** staff on laboratory methods? Yes No

24a What topics are covered during training? (e.g. PCR, Nucleic Acid Extraction): _____

***Please provide additional information in the training table**

25 General comments/notes regarding **molecular biology**: _____

Laboratory Biosafety and Safety

Laboratory Biosafety and Safety

1	Does the facility have a designated safety team? <input type="checkbox"/> Yes <input type="checkbox"/> No
1a	If yes, does the influenza laboratory have a member? <input type="checkbox"/> Yes <input type="checkbox"/> No
1b	Is there a safety officer for the influenza laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No
2	Does the laboratory have a safety manual? <input type="checkbox"/> Yes <input type="checkbox"/> No
2a	If yes, is it easily accessible to all laboratory staff? <input type="checkbox"/> Yes <input type="checkbox"/> No
2b	If yes, is it located in the laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No
2c	If yes, is it reviewed annually? <input type="checkbox"/> Yes <input type="checkbox"/> No
2d	If yes, is it edited/updated to reflect changes? <input type="checkbox"/> Yes <input type="checkbox"/> No
2e	If yes, are laboratory staff required to review and sign indicating their understanding and acknowledgment of safety procedures? <input type="checkbox"/> Yes <input type="checkbox"/> No
3	What source does the laboratory reference for its biosafety guidelines? <input type="checkbox"/> Biosafety in Microbiological and Biomedical Laboratories <input type="checkbox"/> WHO <input type="checkbox"/> National Regulations <input type="checkbox"/> Other (please describe) _____

Laboratory Biosafety and Safety

4	<p>Are staff forbidden from doing the following:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 80%;"></th> <th style="width: 10%; text-align: center;">Yes</th> <th style="width: 10%; text-align: center;">No</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Wearing PPE outside of the laboratory (i.e. coffee room, canteens, etc)?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Wearing open-toed footwear in the laboratory?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Eating, drinking, smoking, or applying cosmetics in the laboratory?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Storing food or drinks in the laboratory working areas?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Mouth pipetting?</td> <td></td> <td></td> </tr> </tbody> </table>		Yes	No	Wearing PPE outside of the laboratory (i.e. coffee room, canteens, etc)?			Wearing open-toed footwear in the laboratory?			Eating, drinking, smoking, or applying cosmetics in the laboratory?			Storing food or drinks in the laboratory working areas?			Mouth pipetting?		
	Yes	No																	
Wearing PPE outside of the laboratory (i.e. coffee room, canteens, etc)?																			
Wearing open-toed footwear in the laboratory?																			
Eating, drinking, smoking, or applying cosmetics in the laboratory?																			
Storing food or drinks in the laboratory working areas?																			
Mouth pipetting?																			
5	<p>Do laboratory staff always use the following PPE (when indicated) when working in the laboratory:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 80%;"></th> <th style="width: 10%; text-align: center;">Yes</th> <th style="width: 10%; text-align: center;">No</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Lab coats?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Gloves?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Shoe covers?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Safety glasses/goggles/visors/face shields?</td> <td></td> <td></td> </tr> <tr> <td style="padding: 5px;">Respiratory Protection?</td> <td></td> <td></td> </tr> </tbody> </table> <p style="margin-top: 10px;">Other (please specify): _____</p> <p>_____</p>		Yes	No	Lab coats?			Gloves?			Shoe covers?			Safety glasses/goggles/visors/face shields?			Respiratory Protection?		
	Yes	No																	
Lab coats?																			
Gloves?																			
Shoe covers?																			
Safety glasses/goggles/visors/face shields?																			
Respiratory Protection?																			
5a	<p>If no to any of the above, why? _____</p>																		

Laboratory Biosafety and Safety

<p>6</p> <p>6a</p>	<p>Is the available PPE appropriate for specific tasks? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, why? _____</p>
<p>7</p> <p>7a</p>	<p>Are <u>powder free</u> gloves worn for all manipulations of specimens, organisms, and reagents? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, are they worn for:</p> <p><input type="checkbox"/> Designated procedures only <input type="checkbox"/> Technician discretion</p>
<p>8</p>	<p>What type of laboratory coats are available for staff (please check all that apply)?</p> <p><input type="checkbox"/> Cloth <input type="checkbox"/> Impermeable <input type="checkbox"/> Cuffed Sleeves <input type="checkbox"/> Disposable <input type="checkbox"/> Properly sized</p> <p><input type="checkbox"/> Other (please describe) _____</p>
<p>9</p>	<p>How are cloth lab coats cleaned?</p> <p><input type="checkbox"/> At the Laboratory <input type="checkbox"/> At home <input type="checkbox"/> Commercially <input type="checkbox"/> Not Applicable</p> <p><input type="checkbox"/> Other (please describe) _____</p>
<p>10</p> <p>10a</p> <p>10b</p> <p>10c</p> <p>10d</p>	<p>Is there a hand washing station inside the influenza laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If not, where is it located? _____</p> <p>If there is not a hand washing station, what is the alternate method? _____</p> <p>Is soap available for hand washing? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Are towels or paper available for hand-drying? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Is the hand washing set up in the laboratory acceptable? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable</p>

Laboratory Biosafety and Safety

11	Is the hand-wash station a hands-free set-up (e.g. operated using foot-pedals)? <input type="checkbox"/> Yes <input type="checkbox"/> No
12	Is there an eye-wash station in the laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No
12a	If no, where is it located? _____
12b	Is the eye-wash station readily accessible? <input type="checkbox"/> Yes <input type="checkbox"/> No
13	Is there a shower in the laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No
13a	If no, where is it located? _____
13b	Is the shower station readily accessible? <input type="checkbox"/> Yes <input type="checkbox"/> No
14	Do laboratory staff receive any safety training (please check all that apply)? <input type="checkbox"/> Chemical <input type="checkbox"/> Fire <input type="checkbox"/> Evacuation <input type="checkbox"/> Natural Disasters <input type="checkbox"/> Other (please describe) _____

Laboratory Biosafety and Safety

15

Please list required and optional vaccines listed in the laboratory vaccination policy:

Vaccines	Required	Optional	Included in Country Immunization Program (i.e. Vaccine Preventable Diseases)

Laboratory Biosafety Level

16

What is the current biosafety level of the facility (please check all that apply)?

	Percentage of Laboratory Space	Availability of Laboratory Space
<input type="checkbox"/> BSL-1	_____	_____
<input type="checkbox"/> BSL-2	_____	_____
<input type="checkbox"/> BSL-3	_____	_____

Laboratory Biosafety and Safety

17

If the facility operates at BSL-2, are the following BSL-2 practices maintained, as defined by *Biosafety in Microbiological and Biomedical Laboratories*:

Restricted access to laboratory? Yes No

Lab personnel provided medical surveillance and immunizations? Yes No

Lab personnel trained on how to handle pathogenic agents? Yes No

Incidents resulting in exposure are immediately evaluated and treated according to biosafety manual procedures? Yes No

PPE is used when handling infectious material? Yes No

BSCs, or other physical containment units, are used? Yes No

BSCs are regularly maintained? Yes No

Designated containers are used for infectious materials? Yes No

Equipment decontaminated before repair/maintenance/removal? Yes No

17a

If no to any of the above, please describe: _____

Laboratory Biosafety and Safety

18

If the facility operates at BSL-3, are the following BSL-3 practices maintained, as defined by the *Biosafety in Microbiological and Biomedical Laboratories*:

Controlled access to laboratory? Yes No

Lab personnel provided medical surveillance and immunizations? Yes No

Lab personnel trained on how to handle pathogenic agents? Yes No

Are all procedures involving infectious material conducted within BCSs? Yes No

Are BSCs regularly maintained? Yes No

Laboratory specific biosafety level 3 manuals are available? Yes No

Incidents resulting in exposure are immediately evaluated and treated according to biosafety manual procedures? Yes No

PPE is used when handling infectious material? Yes No

Autoclave for waste disposal (e.g. 2 door)? Yes No

Designated containers are used for infectious materials? Yes No

Equipment decontaminated before repair/maintenance/removal? Yes No

Is there directional airflow? Yes No

Were facility design, operational parameters, and procedures verified and documented prior to operation? Yes No

Is the facility re-verified and documented at least annually? Yes No

18a

If no to any of the above, please describe: _____

Laboratory Biosafety and Safety

19	If handling H5, is there a respirator fit program? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA, don't handle H5
20	Are PAPRs available for staff that cannot wear N95 respirators? _____ <input type="checkbox"/> Yes <input type="checkbox"/> No
21	Does the laboratory use BSL-3 practices in a BSL-2 laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No
21a	If Yes, please describe: _____ _____
21b	If the laboratory uses BSL-3 practices in a BSL-2 laboratory, are the practices acceptable? _____ <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable

Chemical Safety

22	Does the laboratory have written clean-up instructions for spills? <input type="checkbox"/> Yes <input type="checkbox"/> No												
22a	If yes, are they posted on the walls in the laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No												
23	<p>What chemicals are routinely used for surface decontamination?</p> <table border="1" data-bbox="254 1175 1812 1333"> <thead> <tr> <th>Surface decontaminant</th> <th>Used? (Y/N)</th> <th>Concentration?</th> <th>Length in circulation?</th> </tr> </thead> <tbody> <tr> <td>Ethanol</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Bleach</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>Other (please specify): _____</p>	Surface decontaminant	Used? (Y/N)	Concentration?	Length in circulation?	Ethanol				Bleach			
Surface decontaminant	Used? (Y/N)	Concentration?	Length in circulation?										
Ethanol													
Bleach													

Laboratory Biosafety and Safety

24	<p>Do you disinfect the following on a monthly basis:</p> <p>Centrifuges? <input type="checkbox"/> Yes <input type="checkbox"/> No Incubators? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
25	<p>Are there metal cabinets for flammable chemicals? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
26	<p>Are volumes of acids and bases greater than one liter stored in the laboratory? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
26a	<p>If yes, are they stored separately? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>

Biohazard Disposal

27	<p>Does the laboratory have a written standard operating procedure for proper biohazard disposal? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>																												
28	<p>What treatments are used for biohazard waste disposal?</p> <table border="1" data-bbox="260 967 1820 1328"> <thead> <tr> <th data-bbox="260 967 737 1011">Treatment</th> <th data-bbox="737 967 1096 1011">Solid Waste</th> <th data-bbox="1096 967 1455 1011">Liquid Waste</th> <th data-bbox="1455 967 1820 1011">On site?</th> </tr> </thead> <tbody> <tr> <td data-bbox="260 1011 737 1062">No treatment</td> <td data-bbox="737 1011 1096 1062"></td> <td data-bbox="1096 1011 1455 1062"></td> <td data-bbox="1455 1011 1820 1062" style="background-color: #cccccc;"></td> </tr> <tr> <td data-bbox="260 1062 737 1112">Autoclaving</td> <td data-bbox="737 1062 1096 1112"></td> <td data-bbox="1096 1062 1455 1112"></td> <td data-bbox="1455 1062 1820 1112"></td> </tr> <tr> <td data-bbox="260 1112 737 1162">Incineration</td> <td data-bbox="737 1112 1096 1162"></td> <td data-bbox="1096 1112 1455 1162"></td> <td data-bbox="1455 1112 1820 1162"></td> </tr> <tr> <td data-bbox="260 1162 737 1213">Burial with no pre-treatment</td> <td data-bbox="737 1162 1096 1213"></td> <td data-bbox="1096 1162 1455 1213"></td> <td data-bbox="1455 1162 1820 1213"></td> </tr> <tr> <td data-bbox="260 1213 737 1263">Sharps container</td> <td data-bbox="737 1213 1096 1263"></td> <td data-bbox="1096 1213 1455 1263"></td> <td data-bbox="1455 1213 1820 1263" style="background-color: #cccccc;"></td> </tr> <tr> <td data-bbox="260 1263 737 1328">Chemical disinfection</td> <td data-bbox="737 1263 1096 1328"></td> <td data-bbox="1096 1263 1455 1328"></td> <td data-bbox="1455 1263 1820 1328" style="background-color: #cccccc;"></td> </tr> </tbody> </table> <p data-bbox="260 1360 1906 1393">Other (please specify): _____</p> <p data-bbox="260 1425 1906 1458">_____</p>	Treatment	Solid Waste	Liquid Waste	On site?	No treatment				Autoclaving				Incineration				Burial with no pre-treatment				Sharps container				Chemical disinfection			
Treatment	Solid Waste	Liquid Waste	On site?																										
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Chemical disinfection																													

Laboratory Biosafety and Safety

28a	If the influenza laboratory utilizes autoclaves, is the number of autoclaves sufficient for the amount of biohazardous waste generated? <input type="checkbox"/> Yes <input type="checkbox"/> No
29	Do you always use temperature strips for sterilization? <input type="checkbox"/> Yes <input type="checkbox"/> No
Biosafety Training	
30	Is internal training offered for staff on biosafety methods? <input type="checkbox"/> Yes <input type="checkbox"/> No
30a	What topics are covered during training? _____ _____ _____ *Please provide additional information in the training table
31	General comments/notes regarding safety : _____ _____ _____ _____

Quality Assurance/ Quality Control

Quality Assurance/Quality Control

- 1 Does the laboratory have written standard operating procedures for (check all that apply):
- All assays Sterilization/disinfection procedures Other (please describe) _____
- If applicable, please provide the laboratory's sterilization / disinfection procedures.*

Inventory Control

- 2 Are funds for reagents part of your laboratory's annual budget? Yes No
- 3 Does the laboratory keep records of deliveries of reagents and supplies? Yes No
- 4 Does the laboratory keep an inventory of stock? Yes No
- 5 Are quantities of reagents and materials regularly monitored so that there is a warning if stocks become low? Yes No
- 6 Does the laboratory have a maximum stock level for reagents and consumables? Yes No
- 7 Who determines how much stock to order? _____

Quality Assurance/Quality Control

8	On average, how long does it take from time of ordering to when supplies are available for use? _____																												
8a	Please list any supplies where there are particularly long delays and how long these delays can be. _____ _____																												
9	Does the laboratory have difficulty maintaining inventory of supplies and reagents from outside of the country? <input type="checkbox"/> Yes <input type="checkbox"/> No																												
10	Does the laboratory have difficulty maintaining inventory of supplies and reagents from inside of the country? <input type="checkbox"/> Yes <input type="checkbox"/> No																												
11	How do reagents and supplies arrive at the laboratory? _____ _____ _____																												
12	<p>Please indicate if your laboratory does the following inventory control procedures:</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th style="width: 70%;"></th> <th style="width: 15%; text-align: center;">Always</th> <th style="width: 15%; text-align: center;">Sometimes</th> <th style="width: 10%; text-align: center;">Never</th> </tr> </thead> <tbody> <tr> <td>Regularly check the expiration dates of your reagents?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Write the opening date of the reagents on the containers and kits?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Perform yearly inventories of your stock?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Use expired products and reagents?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Exchange reagents with other labs in case of shortage?</td> <td></td> <td></td> <td></td> </tr> <tr> <td>Reuse consumables?</td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>Is the frequency of the exchange of reagents acceptable? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable</p> <p>Is the frequency of reusing of consumable acceptable? <input type="checkbox"/> Recommendation <input type="checkbox"/> Acceptable</p>		Always	Sometimes	Never	Regularly check the expiration dates of your reagents?				Write the opening date of the reagents on the containers and kits?				Perform yearly inventories of your stock?				Use expired products and reagents?				Exchange reagents with other labs in case of shortage?				Reuse consumables?			
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Quality Assurance/Quality Control

13	<p>Please indicate the following equipment quality assurance procedures your laboratory performs (check all the apply):</p> <table border="1" data-bbox="254 228 1900 625"> <thead> <tr> <th data-bbox="254 228 653 391"></th> <th data-bbox="653 228 1066 391">Back-up equipment is available in case of equipment failure</th> <th data-bbox="1066 228 1482 391">Regularly monitored temperature readings</th> <th data-bbox="1482 228 1900 391">Temperature monitored with certified thermometers (e.g. National Institute of Standards & Technology)</th> </tr> </thead> <tbody> <tr> <td data-bbox="254 391 653 451">Refrigerators (2°C to 8°C)</td> <td data-bbox="653 391 1066 451"></td> <td data-bbox="1066 391 1482 451"></td> <td data-bbox="1482 391 1900 451"></td> </tr> <tr> <td data-bbox="254 451 653 511">Freezer (-20°C)</td> <td data-bbox="653 451 1066 511"></td> <td data-bbox="1066 451 1482 511"></td> <td data-bbox="1482 451 1900 511"></td> </tr> <tr> <td data-bbox="254 511 653 571">Freezer (-80°C)</td> <td data-bbox="653 511 1066 571"></td> <td data-bbox="1066 511 1482 571"></td> <td data-bbox="1482 511 1900 571"></td> </tr> <tr> <td data-bbox="254 571 653 625">Water baths</td> <td data-bbox="653 571 1066 625"></td> <td data-bbox="1066 571 1482 625"></td> <td data-bbox="1482 571 1900 625"></td> </tr> </tbody> </table> <p data-bbox="254 662 1900 743">Other (please specify): _____ _____</p>		Back-up equipment is available in case of equipment failure	Regularly monitored temperature readings	Temperature monitored with certified thermometers (e.g. National Institute of Standards & Technology)	Refrigerators (2°C to 8°C)				Freezer (-20°C)				Freezer (-80°C)				Water baths			
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Refrigerators (2°C to 8°C)																					
Freezer (-20°C)																					
Freezer (-80°C)																					
Water baths																					
14	Does the laboratory have a written preventive maintenance plan and schedule for equipment? <input type="checkbox"/> Yes <input type="checkbox"/> No																				
15	Does the laboratory keep preventive maintenance records for equipment? <input type="checkbox"/> Yes <input type="checkbox"/> No																				
16	Are all automated laboratory equipment calibrated at least annually? <input type="checkbox"/> Yes <input type="checkbox"/> No																				
17	Are all non-automated laboratory equipment (pipettes, heat blocks, etc.) calibrated at least annually? <input type="checkbox"/> Yes <input type="checkbox"/> No																				

Quality Assurance/Quality Control

18	What volume disposable tips does the laboratory currently use? _____ _____
18a	Do the tips used in the laboratory fit the pipettes properly? <input type="checkbox"/> Yes <input type="checkbox"/> No
19	Does your laboratory maintain up to date training records for all personnel ? <input type="checkbox"/> Yes <input type="checkbox"/> No
20	General comments/notes regarding quality assurance : _____ _____ _____ _____ _____ _____ _____ _____ _____ _____ _____

Equipment

Equipment

Please indicate which equipment your laboratory uses in the corresponding section.
Please included additional information as requested.

Equipment	Number Operational	Age (<1yr, 1-5yr, >5yrs)	Current Maintenance Agreement? (Y/N)	Maintenance staff available to fix equipment? (Y/N)	Equipment shared with other labs? (Y/N)	Dedicated to Virology, Molecular biology, RNA only, post PCR, other?	Instrument model?	Instrument manufacturer?	How Frequently are these instruments run? (often, rarely, never)	Do the centrifuge buckets have lids? (Y/N)
Centrifuges:										
Autoclaves:										

Is the maintenance of centrifuges acceptable? Recommendation Acceptable

Are the bucket lids for centrifuges acceptable? Recommendation Acceptable

Is the maintenance of autoclaves acceptable? Recommendation Acceptable

Equipment

Equipment	Number Operational	Age (<1yr, 1-5yr, >5yrs)	Current Maintenance Agreement? (Y/N)	Maintenance staff available to fix equipment? (Y/N)	Equipment shared with other labs? (Y/N)	Regularly check the Kohler centering of the microscope? (Y/N)	Annually Calibrated?
Microscopes:							
Upright for tissue culture							
Immunofluorescence							
50w or 100w mercury?							
Pipettes:							
P2							
P10							
P100							
P200							
P1000							

Is the maintenance of microscopes acceptable? Recommendation Acceptable

Is the calibration of pipettes acceptable? Recommendation Acceptable

Equipment

Equipment	Number Operational	Age (<1yr, 1-5yr, >5yrs)	Current Maintenance Agreement? (Y/N)	Maintenance staff available to fix equipment? (Y/N)	Equipment shared with other labs? (Y/N)	Dedicated to Virology, Molecular biology, RNA only, post PCR, other?	Instrument model?	Instrument manufacturer?	How Frequently are these instruments utilized? (often, rarely, never)	Certified annually? (yes/no)
RT-PCR Instrument(s): _____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____
BSC: _____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____
Incubators: For cell culture	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____
For eggs (non-CO2)	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____
CO2	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____	_____ _____ _____

Are the maintenance agreements on RT-PCR machines acceptable? Recommendation Acceptable

Is the maintenance of BSCs acceptable? Recommendation Acceptable

Are all BSCs certified annually? Recommendation Acceptable

Is the maintenance of incubators acceptable? Recommendation Acceptable

Equipment

Equipment	Number Operational	Age (<1yr, 1-5yr, >5yrs)	Maintenance staff available to fix equipment? (Y/N)	Equipment shared with other labs? (Y/N)	Connected to the internet? (Y/N)	If applicable, how fast is the internet (i.e. Broadband)?
Information Technology:						
Cell phone						
Short Wave radio						
Computers – Administration use only						
Computers – Laboratory use only						
Printers						
Scanners						

Equipment

Equipment	Number Operational	Age (<1yr, 1-5yr, >5yrs)	Current Maintenance Agreement? (Y/N)	Maintenance staff available to fix equipment? (Y/N)	Equipment shared with other labs? (Y/N)	Dedicated to Virology, Molecular biology, RNA only, post PCR, other?
Miscellaneous:						
Freezers (-20°C to -40°C)						
Freezers (-70°C to -80°C)						
Liquid nitrogen						
Refrigerators (2°C to 8°C)						
PCR hood with UV						
Wet Ice machine/ access						
Water Bath						
Vortex						
24-well cooler racks x 2						
96-well cooler racks x 2						
Balance/scales						
pH meter						
ELISA reader						
Spectrophotometer						

Is the maintenance of refrigerators and freezers acceptable? Recommendation Acceptable

Equipment

Equipment	Number Operational	Age (<1yr, 1-5yr, >5yrs)	Current Maintenance Agreement (Y/N)	Maintenance staff available to fix equipment? (Y/N)	Equipment shared with other labs? (Y/N)	Additional Information:
Additional Equipment: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

Training

Training

Training Course	Trainer (name and title)	Type of Training (e.g. lecture, webinar, wet workshop)	How often is the course offered (e.g. daily, weekly, quarterly, yearly)?	Location	Who Participated (e.g. All Staff)	Is training provided for new staff? (Y/N)	Are refresher courses offered? (Y/N)	Is training documented? (Y/N)	Are training records updated regularly? (Y/N)
General: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
Specimen Handling, Collection, and Reporting: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

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Influenza: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
Virology: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

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Molecular Biology: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
Laboratory Safety and Biosafety: <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>

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Comments:									

Capacity Report Template

Capacity Report Template

Influenza Laboratory Capacity Report

Laboratory Name

Country 20xx

Name of Laboratory:	
Address:	
Laboratory Director:	Title Name Surname
Dates of Assessment:	Month day to Month day, 20xx. E.g. July 29 to August 2, 2011
Reviewer/s:	Name Surname, qualifications (e.g. MT(ASCP)), position & institution, email address, telephone number.
Project Officer:	Name Surname
NIC Status:	Designated 20xx or Not designated

1.0 Purpose & Objectives

The purpose of this site visit was to document the capacities of *laboratory name*. The objectives were to:

- 1.1 Meet laboratory staff and key stakeholders, and tour the laboratory.
- 1.2 Complete the *International Influenza Laboratory Capacity Review*.
- 1.3 Provide a report describing the status of laboratory capacity with recommendations for improvement based on data collected through the tool and observation of laboratory practices;
- 1.4 Provide training in... and/or troubleshooting as needed.
- 1.5 Etc. *List others objectives if applicable e.g. Report on recommendations the laboratory has addressed since their last assessment.*

2.0 Background

Please provide a short narrative paragraph about the laboratory which addresses:

Capacity Report Template

- In which year was the laboratory established?
- Does it have any affiliations? (e.g. Ministry of Health, a University, USAID, Pasteur Institute etc.)
- What is the laboratory's primary function? (e.g. Diagnostic, Research, etc.)
- Does it provide other surveillance and/or diagnostic testing besides influenza testing? (e.g. HIV)
- Is it a designated NIC? If yes, in which year was it designated? If not, have they applied for NIC status or are they aspiring to become an NIC?
- Any other pertinent details (e.g. the laboratory has a new Director since *month, year...* The laboratory was relocated to ... *in month, year.* The laboratory was previously called ... and changed its name in year to...)

3.0 Staff and Stakeholders

List the laboratory staff and key stakeholders with whom you met such as, the Laboratory Director, Ministry of Health representatives, CDC in-country contact/s, etc. Include titles (e.g. Ms, Dr, Prof), full names, positions and affiliated institutions. Please include contact information (e.g. email, telephone numbers) for staff or stakeholders not already captured in the tool.

4.0 General Findings

Please **describe** the laboratory's capacity by report section including their strengths and limitations. If this is a repeat assessment, please specify any recommendations from the previous assessment which have been addressed, and how, during the intervening period. For any question-specific comments, please note the relevant question number.

Name	Position	Institution/Affiliation	Contact
Mr. Name Surname	Epidemiologist	WHO	email &/or phone
Dr. Name Surname	Veterinarian	CDC-city	email &/or phone

4.1 General Laboratory

4.2 Specimen Handling, Collection and Reporting

4.3 Virology Laboratory

4.4 Molecular Biology Laboratory

4.5 Laboratory Safety and Biosafety

4.6 Quality Assurance & Quality Control

4.7 Equipment

4.8 Training

5.0 Strengths

Please list the laboratory's strengths and/or improvements in capacity, for example:

5.1 Since *month, year* the laboratory has commenced real-time PCR for detecting and sub-typing influenza viruses including seasonal, 2009 A/H1N1 and H5.

Include in the list any positive responses to the gold-star questions, for example,

5.2 Laboratory uses eggs and cell culture.

6.0 Recommendations

If conducting a re-assessment, please include any previous recommendations made that have not been met.

6.1 Laboratory Recommendations

Please list recommendations for the laboratory for example:

6.1.1 The NIC should store all PCR reagents such as AgPath/Invitrogen kits, primers & probes and PCR control material in NON frost-free freezers (or frost-free freezers where the frost-free function has been disabled).

6.2 Training Recommendations

Please list recommendations for training here:

6.2.1 Train staff on procedures for handling unsubtypable influenza A specimens (e.g. re-testing the specimen to confirm original result, notifying and shipping specimens to a WHO-CC).

7.0 Procurement List

Please list recommended equipment or supplies for the laboratory *in order of importance*, for example:

7.1 PCR workstation (PCR dead-air box) for loading RNA into 96 well PCR plates.

8.0 Acknowledgements

Please include any acknowledgements if applicable.

9.0 Appendices

Attach algorithms, a diagram of the laboratory, SOPs, etc. here. Any photographs should be sent to APHL and CDC along with relevant photo waiver forms (see Appendix 2 for a copy of the form). Appendices should use the following naming convention with an appropriate modifier:

Country.LabName*.Month.Year.LaboratoryReport.Appendix1-shortdescription.

e.g. Bangladesh.IEDCR.Feb2012.LaboratoryReport.Appendix1-LabMap.docx

e.g. Bangladesh.IEDCR.Feb2012.LaboratoryReport.Appendix2-AlgorithmFluA.docx

Acronyms

Acronyms:

AC: air-conditioning	HIV: human immunodeficiency virus	RNA: ribonucleic acid
AFR: WHO Africa Region	IATA: International Air Transport Association	RT-PCR: real-time polymerase chain reaction
AMR: WHO Region of the Americas	ID: identification	SEAR: WHO South-East Asia Region
APHL: Association of Public Health Laboratories	IFA: indirect immunofluorescent antibody test	SOP: standard operating procedure
BSC: biosafety cabinet	IHR: International Health Regulations	STD: sexually transmitted disease
BSL: biosafety level	NGO: non-government organization	TB: tuberculosis
CDC: Centers for Disease Control and Prevention	NIC: National Influenza Centre	UPS: uninterruptable power supply
CO2: carbon dioxide	NIST: National Institute of Standards and Technology	USAID: United States Agency for International Development
DFA: direct immunofluorescent antibody test	PAHO: Pan American Health Organization	UV: ultraviolet
ELISA: enzyme-linked immunosorbent assay	PAPR: powered air purifying respirator	v: volts
EMR: WHO Eastern-Mediterranean Region	PATH: Program for Appropriate Technology in Health (a Seattle-based NGO)	VTM: viral transport medium
EUR: WHO European Region	PCR: polymerase chain reaction	w: watts
GI: gastro-intestinal	PPE: personal protective equipment	WHO: World Health Organisation
GISAID: Global Initiative on Sharing Avian Influenza Data	QA: quality assurance	WHO CC: World Health Organisation Collaborating Centre
HA: haemagglutination test	QC: quality control	WPR: WHO Western Pacific Region
HAI: haemagglutination inhibition test		

Appendix A

Appendix A

Resources:

Biosafety in Microbiological and Biomedical Laboratories, 5th Edition

<http://www.cdc.gov/biosafety/publications/bmb15/index.htm>

International Health Regulations (2005)

<http://www.who.int/ihr/9789241596664/en/index.html>

http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf

WHO Guide for Shipping Infectious Substances (2009)

http://www.who.int/ihr/infectious_substances/en/index.html

Databases and Information Systems

<http://www.who.int/csr/resources/databases/en/index.html>

How to become a National Influenza Centre

http://www.who.int/influenza/gisn_laboratory/national_influenza_centres/how_to_become_a_national_influenza_centre_21_09_2005.pdf

WHO Laboratory Biosafety Manual - 3rd Edition

Multiple Languages:

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

English:

<http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>

African Centre for Integrated Laboratory Training (ACILT) – Training sub-Saharan Africa on Biosafety

<http://www.cdc.gov/globalaids/resources/laboratory/Lab-Training-Center.html>

International Organization of Standardization

<http://www.iso.org>

WHO External Quality Assessment Project for the Detection of Subtype Influenza A Viruses by PCR

http://www.who.int/influenza/resources/documents/EQA_influenza_A_PCR/eqa20070706.pdf

WHO Global Influenza Surveillance and Response Network

http://www.who.int/influenza/gisrs_laboratory/en/

WHO-FluNet

http://www.who.int/influenza/gisrs_laboratory/flunet/en/

Pandemic Influenza Preparedness Framework (includes Terms of Reference for National Influenza Centers, 2011)

http://www.ip-watch.org/weblog/wp-content/uploads/2011/04/PIP-Framework-16-April_2011.pdf

Pandemic Influenza Preparedness Framework – Questions and Answers

http://www.who.int/influenza/pip/PIP_FQA_Nov_2011.pdf

WHO Global Influenza Surveillance Network: Manual for the Laboratory Diagnosis and Virologic Surveillance of Influenza

http://whqlibdoc.who.int/publications/2011/9789241548090_eng.pdf

WHO Influenza Surveillance and Monitoring

http://www.who.int/influenza/surveillance_monitoring/en/

GenBank

<http://www.ncbi.nlm.nih.gov/genbank/>

GISAID

<http://platform.gisaid.org/epi3/frontend#46fe4c>

How to Register for the Influenza Reagent Resource

(IRR): <https://www.influenzareagentresource.org/IRRWebsiteWebinar.aspx>

Appendix B

Appendix B

Suggested Reagents and Supplies

- Invitrogen Catalog #11732-020, SuperScript™III Platinum® One-Step Quantitative RT-PCR Kits
- Ambion Catalog #AM1005, AgPath-ID One-Step RT-PCR Kit
- Positive control viral RNAs (H3N2, H5N1 and Human)
- Forward and reverse primers (40µM) (FluA, H1, H3, H5, FluB, RNP)
- Dual-labeled probes (10µM) (FluA, H1, H3, H5, FluB, RNP)
- 0.2ml PCR reaction tube strips or plates
- Optical strip caps
- Powder-free gloves (small, medium, large)
- Sterile 1.4 ml microcentrifuge tubes 100/pk x 1
- Lint free clean wipes
- Aluminum foil
- Disposable lab coats (Small, Medium, Large)
- Cloth lab coats (Small, Medium, Large)
- Bleach or RNase Away™
- RNA extraction kit : Qiagen viral RNA kit
- 100% reagent grade ethanol
- Water (nuclease free)
- Calculators
- Powder-Free Gloves (Small, Medium, Large)
- Lab Notebooks
- Lint Free Clean Wipes
- Sterile Nuclease Free Filtered Pipette Tips
- Serologic Pipet Aid (Example:Drummond)

The Association of Public Health Laboratories (APHL) is a national non-profit organization dedicated to working with members to strengthen governmental laboratories that perform testing of public health significance. By promoting effective programs and public policy, APHL strives to provide member laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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