

INTERNATIONAL INFLUENZA LABORATORY CAPACITY REVIEW TOOL

Table of Contents

	Worksheet	Worksheet Title	Description
	1	Complete Tool	This is the complete comprehensive tool, consisting of all questions developed for the laboratory assessment.
	2	Equip & Reagents	List of critical reagents and equipment necessary to perform rRT-PCR for influenza.
	3	Contact Info	Module designed to capture relevant contact information.
Purpose: This laboratory capacity assessment tool is intended	4	General Lab	Module designed to assess general laboratory infrastructure and capacity.
to provide guidance to perform a comprehensive laboratory capacity assessment. The tool has been divided into several	5	Vir Lab	Module designed to assess laboratory capabilities and capacities for performing virology.
worksheets, with this excel workbook. There are two comprehensive tools, a "long" form (Complete Tool), "short" form (Influenza Tool), several stand alone modules, and a list of	6	Mol Lab	Module designed to assess laboratory capabilities and capacities for performing molecular biology.
critical equipment and reagents.	7	Flu Testing	Module designed to assess laboratory capabilities and capacities for performing influenza testing.
	8	Safety	Module designed to assess biosafety and biosecurity measures in the laboratory.
	9	Spec Handling & Reporting	Module designed to assess specimen handling procedures and reporting capabilities and capacities.
	10	QA-QC	Module to review quality assurance and quality control measures used in the laboratory



Category	Specific Equipment and Materials	Number Operational	Age	Current Maintanence Contract (Y/N)	Primary Use
equipment equipment equipment equipment	20µL, 200µL, 1000µL adjustable pipettes and aerosol barrier tips (at least 3 each) microcentrifuge bubble centrifuge (2) vortex 24-well cooler racks x 2 96-well cooler racks x 2 PCR hood with UV Biological Safety Cabinet (BSC) (For Each Area) Freezer (-20°C to -40°C) Freezer (-70°C to -80°C) Refrigerator -2°C to 8°C) Floor Centrifuge Microscopes Incubator (CO ₂ Or Non-CO ₂)				
equipment equipment	Water Bath (One For PCR Area, One For Culture Area And For Cell Culture Area) Wet Ice machine/ access				

Equipment & Reagents

Category	Specific Equipment and Materials	Number Operational	Age	Current Maintanence Contract (Y/N)	Primary Use
instruments	real-time thermocycler system				
reagents	Invitrogen Catalog #11732-020, SuperScript™III Platinum® One-Step Quantitative RT-PCR Kits				
reagents	Ambion Catalog #AM1005, AgPath-ID One-Step RT-PCR Kit				
reagents	positive control viral RNAs (H3N2, H5N1 and Human)				
reagents	forward and reverse primers (40μ M) (FluA, H1, H3, H5, FluB, RNP)				
reagents	dual-labeled probes (10μ M) (FluA, H1, H3, H5, FluB, RNP)				
supplies	0.2ml PCR reaction tube strips or plates				
supplies	optical strip caps				
supplies	powder-free gloves (small, medium, large)			·····	
supplies	sterile 1.4 ml microcentrifuge tubes 100/pk x 1				
supplies	Lint free clean wipes				
supplies	Aluminum foil				
supplies	Diposable lab coats (Small, Medium, Large)				
supplies	Cloth lab coats (Small, Medium, Large)				
supplies	Bleach or RNase AwayTM				
supplies	RNA extraction kit : Qiagen viral RNA kit				
supplies	100% reagent grade ethanol				
supplies	Water (nuclease free)				
supplies	Calculators				
supplies	Powder-Free Gloves (Small, Medium, Large)				
supplies	Lab Notebooks				
supplies	Lint Free Clean Wipes				
supplies	Sterile Nuclease Free Filtered Pipette Tips				
supplies	Serologic Pipet Aid (Example:Drummond)				
supplies	Serologic Pipetts				



INTERNATIONAL INFLUENZA LABORATORY CAPACITY REVIEW TOOL

LABORATORY CONTACTS

1	Name of Laboratory	
	Point of Contact	
	Phone	Best Contact
	FAX	Ħ
	Email	Ħ
	Alternate Email (yahoo, gmail, etc.)	H
2	What WHO region is the laboratory located? AFRO WPRO PAHO SEARO EURO EMRO	
3 3a	Is the laboratory a WHO National Influenza Center (NIC)? If No, has the laboratory applied to become a NIC?	Yes No Do not Know/not sure Yes No Do not Know/not sure

4	What country is this laboratory's WHO Influenza Reference laboratory located in?	
5	Which international funding/partner organizations is the laboratory affiliated with?	
	Pasteur	
	AMRO	H
	CDC	H
	USAID	
	WHO	
	PATH Global Health	
	World Bank	
	Other (please specify)	
6	Location of Laboratory Mailing Address (Not PO Box) Phone email FAX Shipping Address (If different from mailing address, Not PO Box)	
7	Contact within Ministry of Health Name	
	Contact information	
	Phone	
	email	
	FAX	

	Does the contact within the MoH speak English? If Yes, conversational English If Yes, scientific English If Yes, fluent English Other spoken languages (please specify)?	Yes No Do not Know/not sure Yes No Do not Know/not sure
8	Laboratory Director Name Contact information	
	Does the Influenza Laboratory Director speak English? If Yes, conversational English If Yes, scientific English If Yes, fluent English Other spoken languages (please specify)?	Yes No Yes No Yes No Yes No Yes No
9	Laboratory Supervisor Name Contact information Phone email FAX	
	Does the Laboratory Supervisor speak English? If Yes, conversational English If Yes, scientific English If Yes, fluent English Other spoken languages (please specify)?	Yes No Yes No Yes No Yes No Yes No

10	Influenza Laboratory Supervisor (if different from above) Same as Laboratory Supervisor Above Name Contact information Phone email FAX	Yes No
	Does the Influenza Laboratory Supervisor speak English? If Yes, conversational English If Yes, scientific English If Yes, fluent English Other spoken languages (please specify)?	Yes No Yes No Yes No Yes No Yes No Yes No
11	Evaluator	
	Signature	
	Date of visit	
12	General Comments/Notes:	

LABORATORY CONTACTS

	SAFER + HEALTHIER + PEOPLE	
	INTERNATIONAL INFLUENZA LABORAT	ORY CAPACITY REVIEW TOOL
	GENERAL LABOR	RATORY
1	What is the laboratory's affiliation/designation? Ministry of Health National Laboratory University Laboratory Hospital Laboratory Other (please specify)	
2	What is the primary function of the laboratory? Research Clinical Other (please specify)	8
3	Is the laboratory a Global Aids Project (GAP) laboratory?	Yes No Do not Know/not sure
4	What infectious disease testing services does the laboratory provide?	
5	Does the laboratory have facilities that maintain and care for animals?	Yes No Do not Know/not sure

GENERAL LABORATORY

5a	If Yes what animals, and what is the purpose of the animals?	
6	Please describe the surveillance activities the laboratory participates in.	
	Please describe the existing information exchange capability(ies) the laboratory has.	
	Does the laboratory appear to be structurally sound (no missing windows doors, etc.)	Yes No
9	Does laboratory equipment appear to be placed appropriately given any structural limitations?	Yes No
	Is the laboratory easily accessible by ground transportation? If No, please explain transportation options	Yes No

11 11a	Is the laboratory supported by a maintenance staff? If Yes, what types of staff: Electrician Mechanical Other (please specify)	Yes No Do not Know/not sure
12	Is there sufficient electrical capacity to power all equipment?	Yes No Do not Know/not sure
13	Does the laboratory have an emergency generator/power?	Yes No Do not Know/not sure
14	Does the laboratory have the capacity to run: 220V 110V Do not Know	
15 15a	Does the laboratory have facilities security measures in place? If Yes what are these measures? Electronic Surveillance (cameras) Manned Surveillance Electronic Security System Front Door Chain Locks ID Badges Require sign-in of visitors Other (please specify)	Yes No
16	Does the laboratory have biosecurity measures in place (prevent internal theft)?	Yes No

16a	If Yes what are these biosecurity measures? ID Badges Freezer locks Restricted access to buildings Cameras Restricted access to laboratories (i.e. BSL 3) Other (please specify)	
17 17a	Does the laboratory have a written biosecurity plan? If No, would you be interested in assistance developing one?	Yes No Yes No
18	Are critical equipment (PCR machines, freezers, etc.) connected to UPS battery backups?	Yes No
19 19a	Is there a 24 hour, 7 day emergency contact, in cases of critical equipment failure or disease outbreaks? If Yes, What is their job title?	Yes No Do not Know/not sure
20	How many hours per day does the laboratory normally operate?	
21	How many days per week does the laboratory normally operate?	
22	What days does the laboratory normally operate?	
23	How many days per year is the laboratory closed for holidays?	

24	Are there specific months where the laboratory is closed for significant time due to holidays or other activities?	Yes No
24a	If Yes, Please specify which one(s)	
25	Does the laboratory have a crisis plan that can be instituted during an emergency (for example during an influenza epidemic)?	Yes No Do not Know/not sure
26	Does the laboratory have a written plan to address surge capacity activities?	Yes No Do not Know/not sure
	If Yes, briefly describe	
26a	If No, is the laboratory interested in assistance for developing one?	Yes No
27	Is there an operational BSL-3 laboratory?	Yes No
28	Is there an operational BSL-2 laboratory?	Yes No
29	Does the laboratory use enhanced BSL-2 procedures?	Yes No
29a	If Yes, describe the BSL-3 enhancements to your BSL-2 facility	
30	How many laboratory staff? Full-time Part-time	

GENERAL LABORATORY

31	Please describe the duties of laboratory staff including; Influenza Testing Supervisor
	Primary Laboratory Technician
	Approximately how many specimens does the laboratory receive for diagnostic testing per week?
33	Approximately how many specimens can the laboratory staff process per week for culture?
33a	Approximately how many specimens can the laboratory staff process per week for PCR?
34	On average how many hours per week do laboratory staff work?
	<30 hours 31 -40 hours 41 - 50 hours > 50 hours
35	How many hours per week does laboratory staff work on influenza testing?

36	Are laboratory staff cross-trained to perform molecular biology and virology?	Yes No Do not Know/not sure
37	Do laboratorians have an office area separate from the laboratory?	Yes No
38	General Comments/Notes:	



INTERNATIONAL INFLUENZA LABORATORY CAPACITY REVIEW TOOL

VIROLOGY LABORATORY

1	Does the virology laboratory perform influenza virus isolation?	Yes No
2 2a	Does the laboratory perform isolation for other viruses? If Yes, please specify which viruses.	Yes No
3	How much experience does the laboratory have performing virus culture? < 6 months 6 - 12 months >12 months	
4	Under normal operating conditions, approximately how many specimens are cultured: Daily Weekly Monthly	
5	Approximately what percent of PCR positive influenza specimens are cultured?	

VIROLOGY LABORATORY

6	Please describe the laboratory's algorithm for culturing specimens:	
7	Does the laboratory use cell culture, eggs, or both?	CC EGGS Both
7a	If using cell culture, what cell lines are being used?	
7b	If using cell culture, what is the source of the cell lines?	
7c	Are cell lines routinely tested for the presence of mycoplasma sp.?	Yes No
8a	Is there a designated clean room for cell culture? If No, where do you perform cell culture?	Yes No
8b	If No, how do you prevent contamination?	
9	Is the virology laboratory performing immunofluorescence testing?	Yes No
	DFA IFA	Kit and Source

Is there virology research conducting in the same laboratory as diagnostic testing?	Yes No
Does the laboratory perform haemagglutination inhibition testing (HAI)? If Yes, does the laboratory use the WHO reagent kit? If Yes, from which WHO Centre?	Yes No Yes No
If Yes, what is your source for red blood cells: Animal Vendor / Source	
Are there separate BSCs designated for: Cell Culture Virus Isolation Avian influenza (i.e. H5N1) non-human influenza	Yes No Yes No Yes No Yes No Yes No
What types of vessels are used for cell culture (check all that apply)? Flask Tubes Shell Vials Other (please specify)	
Does the virology laboratory have microscopes? Upright for tissue culture Immunofluorescence 50w or 100w mercury? Other (please specify)	Ves No Yes No
	testing? Does the laboratory perform haemagglutination inhibition testing (HAI)? If Yes, does the laboratory use the WHO reagent kit? If Yes, from which WHO Centre? If Yes, what is your source for red blood cells: Animal Vendor / Source Are there separate BSCs designated for: Cell Culture Virus Isolation Avian influenza (i.e. H5N1) non-human influenza What types of vessels are used for cell culture (check all that apply)? Flask Tubes Shell Vials Other (please specify) Does the virology laboratory have microscopes? Upright for tissue culture Immunofluorescence 50w or 100w mercury?

15	Does the virology laboratory have vacuum capability? if Yes, internal line? if Yes, vacuum pump? if Yes, are HEPA filters used?	Yes No Yes No Yes No Yes No Yes No Yes Do not Know/not sure
16	Does the virology laboratory have any of the following centrifuges? Microfuge Floor/bench top for handling volumes > 1ml Dedicated to virology?	Current Maintenance Number Agreement Operational Age (Yes/No) Yes No Yes No Yes No
16a	Do the centrifuge buckets have lids?	Yes No Do not Know/not sure
17	Does the virology laboratory have incubators (please check all that apply)? For cell culture For eggs (non-CO ₂) CO ₂ Is temperature monitored with NIST certified thermometers?	Current Maintenance Number Agreement Operational Age Yes No Yes No Yes No Yes No Yes No Yes No
18	Does the virology laboratory have access to the following pieces of equipment? Freezers (-20°C to -40°C) Freezers (-70°C to -80°C) liquid nitrogen Refrigerators (2°C to 8°C)	Ves No Yes No

19	If there is shared freezer space, does virology have a designated shelf or space for: Reagents Controls Archived specimens Other
20	If there is shared refrigerator space does virology have a designated shelf or space for: Reagents Controls Other
21	General Comments/Notes:

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	INTERNATIONAL INFLUENZA LABORAT	ORY CAPACITY REVIEW TOOL
	MOLECULAR BIOLOGY	LABORATORY
1	Is the molecular biology laboratory performing influenza or other viruses detection, typing, or subtyping with the following methods? Real-time (RT-PCR)	Yes No
1a	Conventional PCR If Yes, which kit(s) and manufacturer	Yes No
2	Does the laboratory currently sequence specimens?	Yes No
3	Where in the laboratory is PCR set-up performed? Clean room PCR cabinet Designated area Other (please specify):	
4	Does the laboratory have a uni-directional workflow (pre-amplification to post-amplification) for PCR?	Yes No

5	Are any of the following dedicated for pre-PCR use only? Pipettes Personal protective equipment (PPE) Supplies Reagents Centrifuges Other (please specify)	
6	Is there a designated area for handling RNA?	Yes No
7 7a	What method does the laboratory currently use for RNA isolation / purification? If a kit is employed to purify RNA, please identify which kit and the manufacturer.	
8	Is there a designated area for handling post PCR amplified product?	Yes No
9 9a	What method does the laboratory currently use for DNA isolation / purification? If a kit is employed to purify DNA, please identify which kit and the manufacturer.	
10 10a 10b 10c	What instrument does the laboratory <u>currently</u> use to perform Real-Time PCR? How many of these instruments does the laboratory have? Please identify any additional instruments the laboratory possesses which could be used for Real-Time PCR? How frequently are these instruments run?	Often Rarely Never
11	Does the laboratory have a reliable source for Real-Time PCR reagents and supplies?	Yes No

11a	If Yes please identify the reagent and the source (for example CDC, WHO, Manufacturer, etc.)	Reagent	Source	
12	What pipettes does the laboratory currently use? P10 P100 P200 P1000 Other (please specify)		Number Operational	Number Properly Calibrated
13 13a 13b	What volume disposable tips does the laboratory currently use (please list all)? Do the tips used in the laboratory fit the pipettes properly? Are filtered (aerosol barrier) tips used?	Yes No Yes No		

14	Does the molecular biology laboratory have either of the following centrifuges? Microfuge Floor/bench top for handling volumes > 1ml	Yes No Yes No	Number Operational	Age	Current Maintenance Agreement (Yes/No)
14a	Are any of the centrifuges identified above (please specific): Dedicated to molecular biology? Dedicated for RNA only? Dedicated for post PCR?	Yes No Yes No Yes No			
15	Does the molecular biology laboratory have access to any of the follow pieces of equipment? Freezers (-20°C to -40°C) Freezers (-70°C to -80°C) liquid nitrogen Refrigerators (2°C to 8°C)	Yes No Yes No Yes No Yes No Yes No	Number Operational	Age	Current Maintenance Agreement (Yes/No)
16	If there is shared freezer space, does molecular biology have a designated shelf or space for: Reagents Controls Archived specimens Other	Yes No Yes No Yes No			
17 17a	Are critical reagents (i.e. enzymes) stored in frost free freezers? If Yes, is the automatic defrost disabled?	Yes No Yes No			

18	If there is shared refrigerator space does molecular biology have a designated shelf or space for: Reagents Controls Other	Yes No Yes No
19 19a	Does the laboratory have access to wet-ice? if No, how are samples kept cold at the bench? (when needed)	Yes No
20	What is the laboratory's heat source at the bench? Heat block Water Bath Other (please specify)	
21	Does the laboratory have vacuum capability? if Yes, internal line? if Yes, vacuum pump? if Yes, are HEPA filters used?	Yes No Yes No Yes No Yes No Yes No Yes Do not Know/not sure
22	General Comments/Notes:	

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	INTERNATIONAL INFLUENZA LABORAT	ORY CAPACITY REVIEW TOOL
		STING
1	Is the laboratory currently performing influenza testing for: Human Influenza H5N1 Avian Influenza High Pathogenic Avian Influenza Low Pathogenic Avian Influenza Other Avian Influenza Novel Influenza (for example A/H1N1 swine-like) Other influenza viruses, please specify	Yes No Yes No Yes No Yes No Yes No Yes No Yes No
2 2a	Are laboratory staff aware of what human (seasonal) influenza is currently circulating in their geographical region? If Yes, please identify	Yes No Do not Know/not sure
3	Is the laboratory currently performing influenza virus isolation for: Human Influenza H5N1 Avian Influenza High Pathogenic Avian Influenza Low Pathogenic Avian Influenza Other Avian Influenza Novel Influenza (for example A/H1N1 swine-like) Other influenza viruses, please specify	Yes No Yes No Yes No Yes No Yes No Yes No Yes No

4	What direct detection methods is the laboratory currently using for testing the following influenza viruses? (Please check all that apply)	
4a	Human Influenza (A/H1/ H3, B) Virus Isolation DFA Real Time RT-PCR Conventional PCR Rapid Tests Other (please specify)	
4b	Novel Influenza (for example A/H1N1 swine-like) Virus Isolation DFA Real Time RT-PCR Conventional PCR Rapid Tests Other (please specify)	
4c	H5N1 Avian Influenza Virus Isolation DFA Real Time RT-PCR Conventional PCR Rapid Tests Other (please specify)	
4d	High Pathogenic Avian Influenza DFA Real Time RT-PCR Conventional PCR Rapid Tests Other (please specify)	

4e	Low Pathogenic Avian Influenza	
	Virus Isolation	
	DFA	
	Real Time RT-PCR	
	Conventional PCR	
	Rapid Tests	
	Other (please specify)	
4f	Other Avian Influenza	
41	Virus Isolation	
	DFA	H
	Real Time RT-PCR	H
	Conventional PCR	H
	Rapid Tests	H
	Other (please specify)	
4g	Other influenza viruses	
_	Virus Isolation	
	DFA	
	Real Time RT-PCR	
	Conventional PCR	
	Rapid Tests	
	Other (please specify)	
	What Real-Time PCR instrument(s) is currently being used for influenza	
	testing in the laboratory?	
		None
5a	Instrument Manufacturer	
5b	Instrument Model	
5c	Age	

5d	Under current maintenance agreement ?	Yes No Do not Know/not sure
5e	How frequently are these instruments run?	Often Rarely
		Never
6	What specific primers and probes is the laboratory using for influenza testing?	
	Circulating Human Influenza	
	Novel Influenza	
	Avian Influenza	
	Other Influenza	
6a	What is the source / manufacturer of the primers and probes used for influenza testing?	
	Circulating Human Influenza	
	Novel Influenza Avian Influenza	
	Other Influenza	
7	What is the laboratory's protocol/algorithm for unsubtypable influenza A specimens? Please describe.	

	Please describe how each diagnostic RT-PCR run is set up: Ask for SOP, ask to describe plate set up, etc.	
9 9a 9b 9c	Under normal operating conditions: How many RT-PCR runs can the laboratory execute per day? How many specimens can be typed per day? What percent of your specimens are positive for influenza A?	
10 10a 10b	Will more than one member of the laboratory staff be trained to perform this assay (recommended)? How many full-time staff? How many half-time staff?	Yes No
11 11a	Does the laboratory participate in any surveillance networks? If Yes, please list	Yes No Do not Know/not sure
12	Does the laboratory perform any influenza testing from non-human specimens?	Yes No

12a	If Yes, please describe:
13	General Comments/Notes:

SAFER •		
	INTERNATIONAL INFLUENZA LABORAT	ORY CAPACITY REVIEW TOOL
	LABORATORY SAFETY	& BIOSAFETY
	At what biosafety levels does the laboratory currently operate at (please check all that apply)?	Percentage of Laboratory Space BSL-1 BSL-2 BSL-3 None
2	Is there a safety team/group/advisor?	Yes No
3 3a 3b 3c	Does the laboratory have a safety manual? If Yes, is it easily accessible to all laboratory staff? If Yes, is it reviewed annually? If Yes, are laboratory staff required to sign off on safety procedures?	Yes No Yes No Yes No Yes No
4	Where source does the laboratory reference for its biosafety guidelines? <i>BMBL</i> WHO National Regulations Other (please describe)	

5 5a	Are the BSCs certified for biosafety level 2, as described in the current WHO/ <i>BMBL</i> guidelines? Has the BSC been certified in the past year?	Yes No Yes No
6 6a	Are the BSCs certified for biosafety level 3, as described in the current WHO/ <i>BMBL</i> guidelines? Has the BSC been certified in the past year?	Yes No Yes No
7	What personal protective equipment (PPE) is available to laboratory staff (please check all that apply)? Gloves (latex and powder free) Gloves (other) Lab coats Shoe Covers Safety glasses/visors/face shields Respiratory protection (describe)	
8	Is the available PPE appropriate for specific tasks?	Yes No
9	What type of laboratory coats are available for staff (please check all that apply)? Cloth Impermeable Cuffed Sleeves Disposable Properly sized Other (please describe)	

10	How are cloth lab coats cleaned?	
11	Is there a respirator fit program?	Yes No Do not Know/not sure
12	Are PAPRS available for staff that cannot wear N95 respirators?	Yes No Do not Know/not sure
13	Is there a hand washing station inside of the laboratory?	Yes No
14	Does the hand washing station have foot pedals?	Yes No
15	Is there an eye wash station / shower inside of the laboratory?	Yes No
	Are <u>powder free</u> gloves worn for all manipulations of specimens, organisms, and reagents? If no, is there access to power free gloves?	Yes No
16b	If no, are they worn for Designated procedures only Technician discretion	Yes No Yes No
17 17a	Is there a laboratory vaccination policy for staff? If Yes, for which diseases? Seasonal Influenza TB HBV Other Laboratory Relevant	Yes No
18	Does the laboratory have written and posted spill clean up instructions?	Yes No Do not Know/not sure

19	Does the laboratory have a written SOP for proper biohazard disposal?	Yes No Do not Know/not sure
20	What guidelines does the laboratory reference for biohazard disposal?	
21	Does the laboratory have an autoclave on site?	Current Number Maintenance Operational Age Agreement Yes No
22	Are the number of autoclaves sufficient for the amount of biohazardous waste generated?	Yes No Do not Know/not sure
23	Does the laboratory have access to an incinerator?	Yes No Do not Know/not sure
24	What treatments are used for solid waste disposal? Autoclaving Incineration Burial with no pre-treatment Sharps container Other (describe)	
25	What treatments are used for liquid waste disposal? No treatment Autoclave Chemical disinfection Other (describe)	

26	What chemicals are routinely used for surface decontamination? Ethanol Bleach Other(please describe)	
27	At what concentrations are surface decontaminants kept?	
28	How long are surface decontaminants kept in circulation?	
29 29a	Are there metal cabinets for flammable chemicals? If Yes, are flammables stored in these cabinets?	Yes No Do not Know/not sure Yes No Do not Know/not sure
30	Are acids and bases stored separately?	Yes No Do not Know/not sure
31	General Comments/Notes:	

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	INTERNATIONAL INFLUENZA LABORAT	ORY CAPACITY REVIE	W TOOL
	TRAINING	ì	
1	Is there any routine training for laboratory staff?	Yes No	
1a	If yes, please list all routine training courses		
1b	How frequently is training offered?		
4-	When we wide the metting training (a.g. Que enviored Lab Disector)?		
1c	Who provides the routine training (e.g. Supervisor, Lab Director)?	Training Course	Instructor

2 2a	Is training for staff offered for laboratory methods in virology? What type of training is offered (e.g. wet workshops, lectures, etc.)?	Yes No Do not Know/not sure
2b	What topics are covered during training? (e.g. cell culture, biology)	
2c	How frequently is training offered?	
2d	Where is training given (specific location)?	
2e	Who provides virology training (e.g. CDC, WHO, Supervisor)?	Training Course Instructor
3	Is training for staff offered for laboratory methods in molecular biology?	Yes No Do not Know/not sure
3a	What type of training is offered (e.g. wet workshops, lectures)?	

3b	What topics are covered during training? (e.g. PCR, Nucleic Acid Extraction)	
3с	How frequently is training offered?	
3d	Where is training given (specific location)?	
3e	Who provides molecular biology training (e.g. CDC, WHO, Supervisor)?	Training Course Instructor
4 4a	Does laboratory staff receive training in biosafety? If Yes, what programs (please list all)?	Yes No

4b	Is biosafety training mandatory for all laboratory staff?	
4c 4d	Is biosafety training specific for each task/area? How frequently is biosafety training offered?	Yes No
	Where is biosafety training given (specific location)?	
4e		
4f	Who provides biosafety training (e.g. Supervisor, Biosafety Officer)?	Training Course Instructor
	Does laboratory staff receive any additional safety training (please check all that apply)?	
	Fire Evacuation Natural Disasters	E
	Other (please specify)	

6	Is there training offered to staff for specimen collection, transport, and labeling?	Yes No Do not Know/not sure
6a	How frequently is training offered?	
6b	Where is training given (specific location)?	
6c	Who provides this type of training?	
7	Is there training offered to laboratory staff for specimen logging, processing, and storage?	
		Yes No Do not Know/not sure
7a	How frequently is training offered?	
7b	Where is training given (specific location)?	
7c	Who provides this type of training?	
70		
8	Is there training for staff in shipping infectious substances?	Yes No Do not Know/not sure
8a	How frequently is training offered?	
u		
ᇟ	Where is training given (specific location)?	
8b	where is training given (specific location)?	
8c	Who provides this type of training?	

9	General Comments/Notes:

	ALTER - HEALTHER - PEOPLE
	INTERNATIONAL INFLUENZA LABORATORY CAPACITY REVIEW TOOL
	SPECIMEN HANDLING, COLLECTION, AND REPORTING
1	Does the laboratory have written procedures for: Specimen collection Specimen transport Specimen labeling Yes No Do not Know/not sure Do not Know/not sure Do not Know/not sure Do not Know/not sure Do not Know/not sure
2	What type of Viral Transport Medium (VTM) is used? WHO VTM Commercial VTM Universal Transport medium Do not know/not sure Other VTM (please describe)
3	What types of specimens does the laboratory accept? Nasopharyngeal washes Nasopharyngeal aspirates Nasal swabs Throat swabs Dual nasopharyngeal swabs/ throat swabs Serum Do not Know/not sure Other (please describe)

4 4a	Does the laboratory have written criteria for specimen rejection? Please specify	Yes No Do not Know/not sure
5	Is the cold chain maintained during the shipment of specimens to the laboratory?	Yes No Do not Know/not sure
6	Does the laboratory accept specimens after normal operating hours?	Yes No Do not Know/not sure
7 7a 7b	Is there a responsible official for receiving specimens <u>during</u> normal operating hours? If Yes, what is their job title? If No, who receives specimens	Yes No Do not Know/not sure
8 8a 8b	Is there a responsible official for receiving specimens <u>outside</u> of normal operating hours? If Yes, what is their job title? If No, who receives specimens	Yes No Do not Know/not sure
9	Is there an official area for receiving specimens?	Yes No Do not Know/not sure
10	Does the laboratory provide a unique identifier for all specimens?	Yes No Do not Know/not sure
11	Are there written procedures for specimen logging, processing, and storage?	Yes No Do not Know/not sure

12	Are there written procedures for shipping infectious substances?	Yes No Do not Know/not sure
13	What is the laboratory's policy for shipping infectious substances to WHO, NIC, or other reference laboratories?	
14	How often are isolates sent to WHO collaborating centers? Daily Weekly Monthly	
15	How are isolates chosen for shipping?	
16 16a 16b 16c 16d 16e 16f	Are specimens sent for: Confirmation If Yes, where are they sent? If Yes, how often are batches sent? Further characterization If Yes, where are they sent? If Yes, how often are batches sent?	Yes No Do not Know/not sure Yes No Do not Know/not sure
17	Which vendor is the preferred shipper?	
18	What shipper(s) are located in country?	
19 19a	Does the laboratory experience any problems or difficulties with customs? If Yes, please explain:	Yes No Do not Know/not sure

20	How are specimens stored <u>before</u> diagnostic testing? Refrigeration (2ºC to 8ºC) Freezer (≤ -20 ºC) Liquid nitrogen Do not Know/not sure Other (please specify)	How Long?	
21	What is the laboratory's specimen retention policy for: Specimens testing positive Specimens testing negative Inconclusive Specimens Other Comments:		
22	How does the laboratory track specimens sent for diagnostic testing? LIMS system Software programs installed on computers (i.e. Microsoft Excel) Notebook / Binder Do not Know/not sure Other (please describe)		
23	How long are records maintained?		
24	How are records archived?		
25	How are records backed-up?		
26 26a	Is there restricted access to archived records? If Yes, who has access?	Yes No Do not Know/not sure	

27	How does the laboratory report out results? Electronic Fax Phone Do not Know/not sure Other (please specify)	
28	Does the laboratory have reliable connectivity to report out results (cell phones, landlines, internet)?	Yes No Do not Know/not sure
29	How frequent are diagnostic results reported? Daily Weekly Monthly Do not Know/not sure	
30	Does the laboratory use standardized forms to report lab results?	Yes No Do not Know/not sure
31	Does the laboratory staff know what the reporting requirements are?	Yes No Do not Know/not sure
32	Is the laboratory aware of the reporting requirements under the International Health Regulations (IHR)	Yes No Do not Know/not sure
33 33a	Do test results undergo internal review prior to reporting out? If Yes, briefly describe the internal review process.	Yes No Do not Know/not sure

34	How often are summary reports generated?	
35	Who are diagnostic results reported to? Flu Net WHO Ministry of Health Other (please describe)	
36	If the laboratory has sequencing capability, where is the sequence data deposited? GISAID Genbank Other database (please specify) Not reported Do not Know/not sure	
37 37a	Does the laboratory have the capability to perform phylogenetic analyses? If Yes, please explain	Yes No Do not Know/not sure
38	Does the laboratory assign strain designations to influenza viruses? If Yes, please describe what nomenclature is used (e.g. WHO criteria)	Yes No Do not Know/not sure
39 39a	Is there a policy for rapid notification of reportable influenza cases? If Yes, please describe	Yes No Do not Know/not sure

40	What is the turn around time for reporting diagnostic results from the receipt of the specimen?
41	General Comments/Notes:

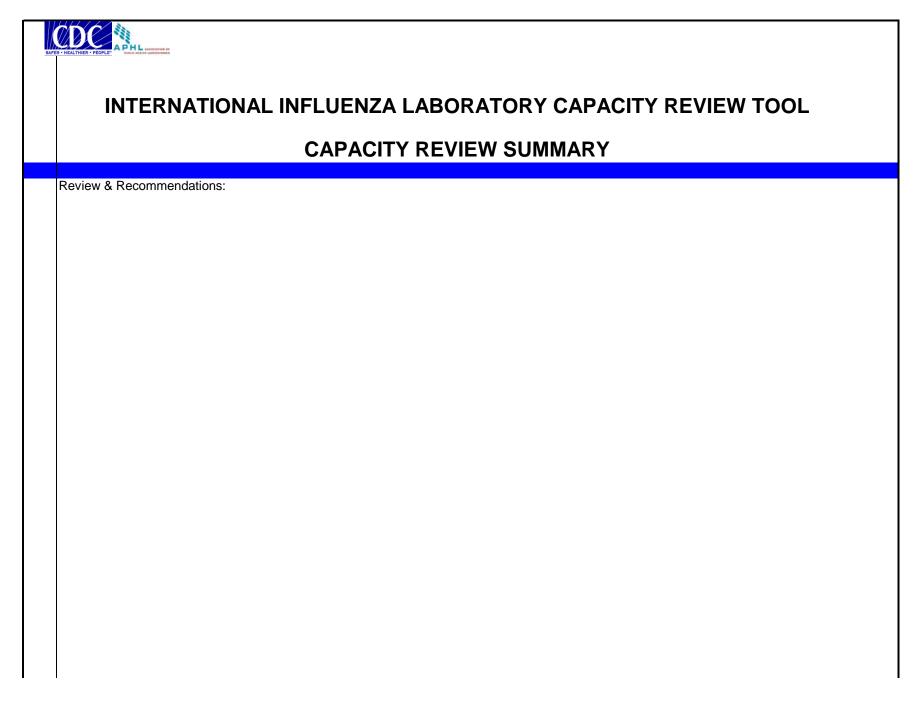
	INTERNATIONAL INFLUENZA LABORATORY CAPACITY REVIEW TOOL		
	QUALITY ASSURANCE		
1	assays?	/es No Do not Know/not sure	
2	Are records kept of the number and type of tests performed and results?	/es 🔲 No 🔲 Do not Know/not sure	
3	3 Does the laboratory have written QC procedures?	/es No Do not Know/not sure	
4	4 Does the laboratory QC all reagents and standards?	/es No Do not Know/not sure	
5	8°C, etc.)	res No Do not Know/not sure	
6	monitored for failures?	/es No Do not Know/not sure	

7	Does the laboratory have back-up refrigerators and freezers in case of an equipment of power failure? (please indicate all) Refrigerators (2°C to 8°C) Freezer (-20°C) Freezer (-80°C)	Yes No Do not Know/not sure Yes No Do not Know/not sure Yes No Do not Know/not sure Yes No Do not Know/not sure
8	Are temperature readings regularly monitored for Refrigerators (2°C to 8°C) Freezer (-20°C) Freezer (-80°C) Water baths Other (please specify)	YesNoDo not Know/not sureYesNoDo not Know/not sureYesNoDo not Know/not sureYesNoDo not Know/not sureYesNoDo not Know/not sure
9	Does the laboratory a have written preventive maintenance plan and schedule for equipment?	Yes No Do not Know/not sure
10	Does the laboratory keep preventive maintenance records for equipment?	Yes No Do not Know/not sure
11	Are all mechanical laboratory equipment calibrated at least annually?	Yes No Do not Know/not sure
12	Are all non-mechanical laboratory equipment (pipettes, heat blocks, etc.) calibrated at least annually?	Yes No Do not Know/not sure
13	Is all critical laboratory equipment currently under manufacturer service or maintenance agreements?	Yes No Do not Know/not sure

14 14a	Are all critical laboratory equipment connected to UPS backups? Yes No Do not Know/not sure Comments
15 16	Does the laboratory have written sterilization/disinfection procedures? Yes No Do not Know/not sure Please describe the laboratory's sterilization / disinfection procedures.
17 17a	Does the laboratory have a protocol to monitor contamination? If Yes, please describe:
18	Is there task-specific dedication and separation of: Pipettes Yes No Do not Know/not sure PPE Yes No Do not Know/not sure Instrumentation Yes No Do not Know/not sure Equipment Yes No Do not Know/not sure Supplies Yes No Do not Know/not sure Reagents Yes No Do not Know/not sure
19	Does the laboratory use any system for an internal quality control? If Yes, please describe:

20 20a 20b	Are internal controls included in each test run? If Yes, is the performance of these internal controls recorded and monitored over time? If Yes, are there acceptance / rejection criteria?	Yes No Do not Know/not sure Yes No Do not Know/not sure Yes No Do not Know/not sure
	Does the laboratory participate in any external quality assurance or proficiency programs? If Yes, please list programs	Yes No Do not Know/not sure
22	Does the laboratory keep records of deliveries of reagents and supplies?	Yes No Do not Know/not sure
23	Does the laboratory keep records to track stock inventory?	Yes No Do not Know/not sure
24	Are quantities of reagents and materials regularly monitored so that there is a warning if stocks become low?	Yes No Do not Know/not sure
	Does the laboratory have a set maximum stock level for reagents and consumables above which inventory level should not go?	Yes No Do not Know/not sure
26	Who determines how much to order?	

27	Under normal circumstances, how long does it take from time of ordering to when supplies are available for use?	Do not Know/not sure
28	Does the laboratory have difficulty maintaining inventory of supplies and reagents from outside of the country?	Yes No Do not Know/not sure
29	Does the laboratory have difficulty maintaining inventory of supplies and reagents from inside of the country?	Yes No Do not Know/not sure
30	How do reagents and supplies arrive at the laboratory?	
31	General Comments/Notes:	



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