

Standard Operating Procedure

Title: External Quality Assurance Program for the CDC Lab-Based Influenza Surveillance Project

Purpose:

To provide an external quality assurance (EQA) mechanism for the immunofluorescent (IF) staining procedures that are utilized in Pacific Island Countries and Territories (PICT) detecting Influenza A, Influenza B, and RSV. This EQA will involve the following parties:

Responsibilities:

WHO-CC: Melbourne (WHO Collaborating Center for Influenza)	- To prepare and ship the EQA testing specimens - To provide technical assistance and follow-up as needed
PICT (Pacific Island Countries – Territories)	- To perform EQA testing as instructed - To submit test results to SPC
SPC: Noumea (Secretariat of the Pacific Community)	- To grade EQA results and provide initial reports back to PICT - To evaluate EQA performance and provide appropriate follow-up to PICT, as needed
PPTC: Wellington (Pacific Paramedical Training Center)	- To tabulate results and include in comprehensive laboratory EQA result reports

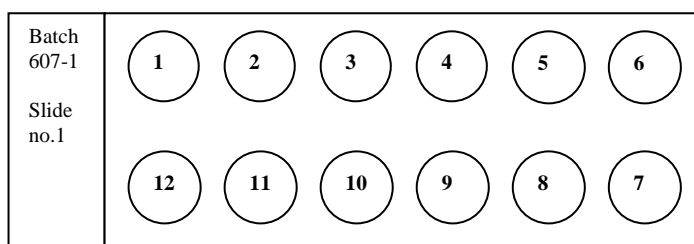
Materials:

Refer to the Flu Project procedures for all staining, reading, interpretation, and microscopy requirements.

Procedure:

A. Specimen preparation – To be performed by WHO-CC

1. EQA specimens will be prepared and mailed, every 6 months, to countries participating in the CDC project
 - a. Each specimen shipment will consist of 9 identical glass slides with 12 wells on each slide
 - b. The wells have specimens dried onto them which represent unknown positive and negative patient samples to be tested for Influenza A, Influenza B and RSV.



B. Slide staining and examination – To be performed by the PICT lab

2. Select 3 slides for the EQA testing
 - a. Any 3 can be selected as all 9 slides are identical
 - b. The remaining 6 slides can be saved for EQA repeat testing or for training purposes
3. Label the slides as follows: Slide 1: #1-Flu A; Slide 2: #2-Flu B; Slide 3: #3-RSV
4. Fix the slides with acetone (refer to the Flu project-specimen staining and reading procedure)
5. After fixing in acetone, allow all 3 slides to air-dry completely

6. Follow the flu project procedure in staining patient specimens for Influenza A, Influenza B, and RSV. Instead of following the staining pattern in the procedure, stain the EQA slides as follows:
 - a. **For slide 1 (#1-Flu A): stain all 12 wells with only Influenza A reagent**
 - R1a-anti Flu A antibody followed with R3-anti Flu A +B conjugate
 - b. **For slide 2 (#2-Flu B): stain all 12 wells with only Influenza B reagent**
 - R1b-anti Flu B antibody followed with R3-anti Flu A +B conjugate
 - c. **For slide 3 (#3-RSV): stain all 12 wells with only RSV reagent**
 - R1-anti RSV antibody
 7. There is no need to include a separate negative control as the staining format of the 3 slides will provide the necessary negative controls
 8. Examine and interpret the slides as you would normally examine patient specimens (refer to the Flu project-specimen staining and reading procedure).
 9. Use the CDC Flu Project EQA Report Form (see attachment 1, below) to report EQA results. Fill in all the information in section A (lab information). Record the results from the 3 slides in section B (stain results).
 10. The EQA report sheet can also be downloaded from the PPHSN website
- C. Reporting of results – to be performed by the PICT lab
11. Submit the completed EQA Report Form to SPC. The information can be either sent by e-mail or by fax to the following:
 - e-mail: melissap@spc.int or albertg@spc.int or justusb@spc.int
 - fax: 687 26 38 18 attn: Public Health-Epidemiology-attn: Justus Benzler
- D. Scoring and reporting of results – to be performed by SPC, PPTC
12. All specimens must be stained and reported by the deadline date:
Within 10 working days from date specimens are received in your lab.
 13. Results not received by the deadline will not be included in the performance scoring for the shipment and will reflect as a failure of the EQA performance.
 14. Results will be evaluated in comparison to the known values established at the WHO-CC. An overall performance score, based on all correct responses, will be provided.
 15. EQA participants must achieve a score of 80% or greater to demonstrate satisfactory performance
 16. An initial report of the EQA test results will be provided to the PICT after each submission
 17. These EQA performance results will also be included in the comprehensive laboratory EQA results that are tabulated and sent out by PPTC.
 18. SPC and WHO-CC will work with participants, that were not able to achieve the desired results, on test troubleshooting mechanisms and appropriate follow-up activities.

Attachment 1

CDC FLU PROJECT EQA REPORT FORM

****DEADLINE DATE FOR REPORTING:**

WITHIN 10 WORKING DAYS FROM DATE SPECIMENS ARE RECEIVED IN YOUR LAB

A. Lab Information:

Country	
Laboratory	
Name of Tech Performing EQA Test	
EQA Specimen Batch No.	
Date EQA Specimen Rec'd in Lab	
Date EQA Specimen Stained and Read	

B. Stain Results:

Batch No.	1	2	3	4	5	6
Slide 1						
Flu A	12	11	10	9	8	7

Batch No.	1	2	3	4	5	6
Slide 2						
Flu B	12	11	10	9	8	7

Batch No.	1	2	3	4	5	6
Slide 3						
RSV	12	11	10	9	8	7

Comments:

Send Completed EQA Results To:

e-mail: melissap@spc.int or albertg@spc.int or justusb@spc.int

fax: 687 26 38 18 attn: Public Health-Epidemiology-attn: Justus Benzler