Appendix XVIII

QUALITY CONTROL OF MONOCLONAL ANTIBODIES

Monoclonal Antibodies	Method	Expected Use
Respiratory Viral Screen/RSV panel FluA/B panel RSV/para3 panel Para123/Adeno panel Specific Parainfluenza 1 Specific Parainfluenza 2	SimulFluor DFA SimulFluor DFA SimulFluor DFA SimulFluor DFA DFA DFA	Tube culture / direct specimen
Coxsackie A9 Coxsackie B Echovirus Poliovirus Enterovirus 70 / 71 Mumps (not in routine use)	IFA	Tube culture
CMV pp65 CMV Immediate Early	IFA IFA	Direct polymorph, leukocytes shell vial
Specific Herpes simplex 1 Specific Herpes simplex 2 Specific Varicella zoster virus CMV early & late Herpes simplex bivalent	DFA	Shell vial / tube / direct specimen Shell vial / tube / direct specimen Shell vial / tube / direct specimen Tube Shell vial / tube / direct specimen

Appendix XVIII (Cont'd)

QUALITY CONTROL OF MONOCLONAL ANTIBODIES

Reagent quality controls:

These must be perform prior to patient testing to ensure each component of the reagent performs as expected.

a. Check expiratory date then perform DFA, SimulFlour DFA or IFA accordingly.
b. External QC slides (different manufacturer, unless not available) of the same batch are used to test both current and the new reagents in parallel
c. Results must fall within range of expected results before reagents are released for use (eg. all 7 viruses must be positive and negative wells are negative for the Bion 14-well Respiratory Panel).
d. Record reagent expiry date and QC results in Reagent Log and/or LIS.
e. Report abnormal QC results to Charge/Senior technologist.

Expected reagent QC results:

External (commercial) QC slide	Current Reagent	New Reagent
Positive well (for each virus)	+	+ (no weaker than current reagent)
Negative well	-	-

Failed reagent QC results:

i. Inform charge/senior technologist to investigate cause of failed QC.
ii. Record in Reagent Log Chart. (Instrument Maintenance Log if microscope/incubator is involved in the failure and Incident Report if necessary).
iii. May need to re-run failed control materials in parallel to fresh controls to evaluate the QC material itself.

iv. If the re-run shows the old QC material still fails and fresh QC is satisfactory, the error may be attributed to the old QC material itself and the reagent is satisfactory.

v. If the re-run shows both the old and fresh QC material fail (or other QC not satisfactory), the error may be attributed to the reagent then the reagent cannot be released for use. Supplier of the reagent should be contacted and the appropriate incident report should be filled.

Daily QCs:

These are performed within each batch of patient samples to monitor assay performance and techniques within the batch.

a. Check reagent expiratory date and verify that Reagent QC is satisfactory for the reagent lot/kit being used.

b. Appropriate positive and negative control slides (eg. ATCC 4-well slide with RSV/Para3 for SimulF RS stain) should be stained with each batch. These slides should be placed in various random positions within the batch.

c. Examine the negative control well first to establish the dull red colour (Evans blue counterstained) and to determine if there is any nonspecific staining.
The positive control must be clearly distinguishable from the negative control or the test is invalid.

d. Record QC results in LIS and/or wosksheet.

Failed Daily QC:

i. Do not release patient results pending resolution of QC error.
ii. Inform charge/senior technologist.
iii. Record in Reagent Log Chart (and Instrument Maintenance Log if microscope/incubator is involved in the failure).
iv. Re-run failed controls in parallel to fresh controls (and/or external QC) to evaluate the QC material itself.
v. If the re-run shows the old QC material still fails, fresh QC passes and nothing else is wrong with the batch (only the old QC material failed, patient results valid) patient results may be released.

Marked decrease/absence in fluorescence can be due to:

a. Reagent deterioration/skipping (did not apply primary/secondary stain)
b. Microscope (filter, bulb, alignment)
c. Other equipment, reagents or technique