Appendix I

REAGENTS/KITS

Chemical Reagents

1. Formaldehyde, Sigma
2. Sucrose, Sigma
3. Nonidet, ICN (changed to IGEPAL CA-630, Sigma cat. # 198596)
4. Ammonium Chloride powder, Sigma
5. Potassium bicarbonate, Sigma
6. DMSO freezing Medium, Sigma
7. Phosphate Buffered Saline (PBS):
   - 8.06 g/L Sodium Chloride
   - 0.20 g/L Potassium Chloride
   - 1.36 g/L KH_2PO_4
   - 1.42 g/L Na_2HPO_4
   - Adjust pH to 7.4 and autoclave.

Reagent Kits

1. FITC – Anti Mouse-(Intermedico, Bartels, Dade-Behring)
2. Herpes simplex I and II DFA-(Dade-Behring)*
3. Varicella zoster DFA-(Oxoid)*
4. CMV, DFA-Bartels (Intermedico)
5. CMV Early Antigen (CMVEA), IFA-Bartels (Intermedico)*
6. Herpes simplex Bivalent DFA-Intermedico*
7. Pan-Enterovirus Blend-(Chemicon)
8. Anti-Echovirus-(Chemicon)
9. Anti-Coxsackie A9-(Chemicon)
10. Anti-Coxsackie B Blend-(Chemicon)
11. Anti-Enterovirus Blend 70/71-(Chemicon)
12. Anti-Poliovirus Blend-(Chemicon)
13. Clonab®, CMV pp 65, Biotest-(RWR Scientific)*
14. Respiratory Virus Antibody Pool – Bartels (Intermedico)
15. Adenovirus Antibody – Bartels (Intermedico)
16. Anti-Influenza A Monoclonal Antibody – Bartels (Intermedico)
17. Anti-Influenza B Monoclonal Antibody – Bartels (Intermedico)

18. Anti-Parainfluenza 1 Monoclonal Antibody – Bartels (Intermedico)
19. Anti-Parainfluenza 2 Monoclonal Antibody – Bartels (Intermedico
20. Anti-Parainfluenza 3 Monoclonal Antibody – Bartels (Intermedico)
21. Anti-RSV Monoclonal Antibody-Bartels (Intermedico)
22. Anti-Adenovirus Antibody-Bartels (Intermedico)
23. Anti-measles Antibody-(Chemicon)
24. SimulFluor DFA Respiratory Viral Screen/RSV panel-(Chemicon)*
25. SimulFluor DFA FluA/B panel-(Chemicon)
26. SimulFluor DFA RSV/para3 panel-(Chemicon)
27. SimulFluor DFA Parainfluenza 1,2,3/Adeno panel-(Chemicon)
28. Specific Parainfluenza 1 DFA-(Chemicon)
29. Specific Parainfluenza 2 DFA-(Chemicon)

Reagent Quality Control:

Performed prior to patient testing and must fall within range of expected results before reagents are released for use. External QC materials are used unless not available. QC materials supplied with reagent kits (usually used as daily QC) must also be done (may be done with the first batch of testing if external QC passes).

Reagent Quality Control Procedure:

a. Check and make sure received date, expiratory date and lot number are recorded in the Reagent Log as well as in LIS micqc.
b. Perform the assay to verify that the results are satisfactory for the reagent lot/kit and record in Reagent Log, and/or LIS and/or on the kit.
c. Use external QC materials (different supplier and to test all components e.g. Bion 14-well Respiratory Panel slides for SimulFluor Resp Screen).
d. Record QC results in Reagent Log and/or LIS as appropriate.
e. Record “in use” date in Reagent Log, and/or LIS (by entering lot active:“yes”) and/or on the kit when placed in service.

Failed Reagent QC:

Test is invalid without satisfactory Reagent QC results.

a. Do not release reagent lot for use pending resolution of QC error.
b. Inform charge/senior technologist.
c. Record in Reagent Log Chart, Instrument Maintenance Log if microscope/incubator is involved in the failure (and Incident Report if necessary).

d. Re-run failed control materials in parallel to fresh controls to evaluate the QC material itself.
e. 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.
f. 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.