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| Rapid Molecular Quality Control and Wipe Testing Reference Procedure  |
| **Purpose** | This procedure provides instructions for quality |
| **Policy Statements** | This procedure applies to laboratory personnel who perform testing on the Cepheid GeneXpert and BioFire FilmArray. |
| **Materials** |  |  |  |  |
|  | **Reagents\*** | **Supplies** | **Equipment** |
|  | * Xpert testing kits
* FilmArray testing kits
* Quality control material

\*See individual SOPs for product specific information and storage conditions.  | * DI water
* Nuclease free water (NFW)
* 70% ethanol
* VTM
* Xpert testing collection tubes
* Eswab collection kits
* Bleach wipes
* Culturette swabs
* Nitrile gloves
* Absorbant cloths
 | * Vortex
* Microfuge
* Cepheid GeneXpert
* BioFire FilmArray
 |
| **Sample** | * Cepheid GeneXpert and BioFire FilmArray assay:
	+ Positive and Negative controls
	+ Wipe testing samples
 |
| **Special Safety Precautions** | Microbiologists are subject to occupational risks associated with specimen handling. Refer to the safety policies:1. [*Biohazard Containment*](file:///G%3A%5CLab%20Procedures%5CMicrobiology%5C1NEW%20Micro%20Procedure%20Manual.%20%28same%20as%20in%20Starnet%29%5CMCVI%203%20Safety%5CMCVI%203.1%20Biohazard%20Containment.docx)
2. [*Safety in the Microbiology Laboratory*](file:///G%3A%5CLab%20Procedures%5CMicrobiology%5C1NEW%20Micro%20Procedure%20Manual.%20%28same%20as%20in%20Starnet%29%5CMCVI%203%20Safety%5CMCVI%203.2%20Safety%20in%20the%20Microbiology%20Lab.docx)
* [*Biohazardous Spills*](file:///G%3A%5CLab%20Procedures%5CMicrobiology%5C1NEW%20Micro%20Procedure%20Manual.%20%28same%20as%20in%20Starnet%29%5CMCVI%203%20Safety%5CMCVI%203.4%20Biohazardous%20Spills.docx)
 |
| **Quality Control** | **External Quality Control:*** Perform QC using external positive and negative controls every 30 days
* Record results in the GeneXpert assay QC binder
* See IQCP document
* See Quality Control Procedure

**New Lot/Shipment Quality control:*** Perform QC using external positive and negative controls with each new lot or shipment before putting into service
* Record results in the GeneXpert assay QC binder
* See Quality Control Procedure

**Wipe testing control:*** Perform wipe testing every 30 days to monitor for contamination
* Record results in the GeneXpert assay QC binder
* See Quality Control Procedure

**NOTE:** External quality control may be performed on an as needed basis if certain circumstances arise. Examples include:* Drift in results (e.g., increasing/decreasing positivity rates)
* Potential contamination (negative control)
* After drastic system maintenance
	+ **NOTE:** File copy of results with the manufacturer’s report in the maintenance binder for each respective instrument.

**NOTE:** New shipments/lots of reagents must be testing with QC material already in use. In the event that only unopened QC material is available, a previously tested positive and negative sample will be tested prior to placing the kits into use. |
| **Procedure** | Maintain inventory control records for reagents and commercial kits as follows:**Table 1: QC Activities and Actions**

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|  | **Activity** | **Action** |
| a | Reagents/kits arrive | a. Record on Inventory/QC logs * Date of receipt
* Lot number(s)
* Quantity

b. Verify proper shipping conditions* Contact technical specialist and purchasing buyer if conditions not acceptable, document
 |
| b | Reagents/Kits are received | Date and place a pinke “New Shipment” label on box  |
| c | QC is verified | Record date performed in QC log book; fill out and place a green “Ready for Use” label on box  |
| d | Placed in service | Record date in QC log book |
| e | QC fails | 1. Document failure and corrective action in problem logs
2. Notify section technical director or designee
3. Do not use reagents for patient testing
4. Notify manufacturer for further instruction or replacement
5. Discard reagents after notification if no further testing will be performed
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Maintain wipe testing records for reagents and commercial kits as follows:**Table 2: Wipe Testing Activities and Actions**

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|  | **Activity** | **Action** |
| a | Adhere to maintenance log schedules  | 1. Check logs daily
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| b | Perform wipe testing | 1. Monthly, per procedure
2. Record date, reagent and supply lot/exp information on wipe testing log
 |
| c | Verify negative results  | Record results on wipe testing log, check off maintenance log  |
| d | Placed in service | Record date in QC log book |
| e | Wipe testing failure (positive) | Notify section technical specialist or director 1. Retest sample
2. Repeat testing using additional swabs (expand individual testing sites)
3. If still positive, decontaminate with 1% v/v bleach/Alconox cleaning solution
4. Repeat testing to verify negative results, contact vendor if results are still positive
5. Review any potentially impacted patient results
6. Document failure and corrective action in problem logs
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**See QC and wipe testing guide below in Table 3:****QC NOTES:** * Positives controls are to be set up before negative controls.
* Modules used to perform QC are to be rotated.
* For GeneXpert QC: under "Test Type" field, select either "Positive Control 1" or "Negative Control 1". Denote the reason for QC in the “Notes” field.

**Wipe testing NOTES:*** Xpert assays: swab the processing hood surface, counter around the GeneXpert instrument (including the keyboard, mouse, and scanner), and door handles on the instrument
* FilmArray assays: swab working areas including processing hood surface, vortex and any other high touch surfaces in the sample prep area.
* Refer to **Table 3** for full instructions.
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**Table 3: QC and Wipe Testing Guide**

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| **Assay** | **QC Material** | **New Lot/Ship, 30 day QC** | **Wipe Testing** |
| **Xpert MRSA NxG** | Microbiologics MRSA/MRSA NxG Control Panel (Cat. No. 8195) Positive: Methicillin Resistant Staphylococcus aureus derived from NCTC 12493 Negative: Staphylococcus epidermidis derived from NCIMB 8853 | **Materials:** Pos/Neg controls, two sample reagent vials, two test cartridges. **Steps:** Label sample reagent vials and break off respective swab into each vial. Vortex for 10 seconds. Using a sterile pipet, transfer all liquid into the proper cartridge. Run as a patient sample. | **Material(s):** eSwab **Steps:** dip the swab in transport media and swab the wipe check areas. Break swab into tube using orange barrier wipe and run as patient sample. \*\*Same tube can be used for Strep A wipe testing.  |
| **Xpert Strep A** | Microbiologics Group A Streptococcus (GAS) positive controls and negative controls (Cat. No. 8219) | **Materials:** Pos/NEG controls,two test cartridges, two eSwabs.**Steps:** Label eSwab tubes and break off respective control swabs into each tube. Vortex for 10 seconds. Using the included kit pipet, transfer eSwab media into the proper cartridge. Run as a patient sample.  | **Material(s):** eSwab **Steps:** See MRSA NxG above.  |
| **Xpert CTNG** | Microbiologics Cepheid Xpert CT/NG positive and negative controls (Cat No. 8188) | **Materials:** Pos/Neg controls, two CT/NG cartridges, two pink-capped Xpert specimen collection tubes**Steps:** Label tubes and cartridges, break off control swab into proper tube. Vortex for 10 seconds. Using the included kit pipet, transfer tube media into the proper cartridge. Run as a patient sample.  | **Material(s):** pink-capped Xpert Vaginal/Endocervical Specimen Collection Kit and sterile fibroblast suspension. **Steps:** wet kit swab in the transport media from the tube and swab wipe check areas. Dip the same small swab into a sterile suspension of fibroblasts. Break off swab into tube using orange barrier wipe and run as patient sample. \*\*Same tube can be used for TV wipe testing. |
| **Xpert TV** | Microbiologics Cepheid Xpert TV positive and negative controls (Cat. No. 8189)  | **Materials:** Pos/Neg controls, two TV cartridges, two pink-capped Xpert specimen collection tubes**Steps:** Label tubes and cartridges, break off control swab into proper tube. Vortex for 10 seconds. Using the included kit pipet, transfer tube media into the proper cartridge. Run as a patient sample. | **Material(s):** pink-capped Xpert Vaginal/Endocervical Specimen Collection Kit and sterile fibroblast suspension. **Steps:** See CTNG testing above.  |
| **Xpert C. difficile-Epi** | Microbiologics C. difficile Positive and Negative Controls (Cat. No. 8200) | **Materials:** Pos/Neg controls, two sample reagent vials, two test cartridges. **Steps:** Label sample reagent vials and break off respective swab into each vial. Vortex for 10 seconds. Using a sterile pipet, transfer all liquid into the proper cartridge. Run as a patient sample. | **Material(s):** sterile Cepheid swab, nuclease free water (found in Molecular fridge) **Steps:** wet the swab with nuclease free water, swab wipe check areas. Process and run as a patient sample.  |
| **Xpert SARS-CoV-2** | SeraCare Accuplex SARS-CoV-2 – Positive and Negative Controls (Cat no. 0505-0126) | **Materials:** Pos (red cap) and Neg (clear cap) controls, two test cartridges**Steps:** Let controls come to room temp and label the test cartridges. (Controls can be used up to 5x, label with open date) Vortex controls for 10 seconds. Using kit pipet, transfer control material to proper cartridge. Run as a patient sample. | **Material(s):** VTM tube, Culturette swab **Steps:** Moisten swab in VTM, swab wipe check areas. Break swab off into a VTM tube using orange barrier wipe. Process and run as patient sample. \*\*Same tube can be used for Flu/RSV and SARS-CoV-2/Flu/RSV *plus* wipe testing. |
| **Xpert Flu and Flu-RSV**  | Microbiologics Cepheid Xpert Respiratory Control Panel – Positive and Negative Controls (Cat. No. 8199) | **Materials:** Pos/Neg controls, two test cartridges, two 3mL UTM tubes**Steps:** Label cartridges and UTM tubes for the positive and negative controls. Break proper swab into the respective UTM tube using an orange barrier wipe. Vortex each tube for 10 seconds. Using kit pipet, transfer control material to proper cartridge. Run as a patient sample. | **Material(s):** VTM tube, Culturette swab **Steps:** See SARS-CoV-2 above.  |
| **Xpert Xpress SARS-CoV-2, Flu and RSV *plus*** | ZeptoMetric NATtrol Flu/RSV/SARS-CoV-2 External Run Controls Positive Controls: Cat. No.NATFRC-6CNegative Controls: VTM | **Materials:** Positive control, Negative Control (UTM aliquot), two test cartridges**Steps:** Label the cartridges. Using a kit pipet, transfer control media to the proper cartridges. Run as a patient sample. | **Material(s):** VTM tube, Culturette swab **Steps:** See SARS-CoV-2 above. |
| **Xpert Enterovirus (EV)** | Enterovirus positive control (made in-house with ZeptoMetrix Coxsackievirus A9 or Echovirus Type 9 culture fluid) Enterovirus negative control (SeraCare synthetic CSF, Cat. No. 0175-0007) | **Materials:** Positive and Negative Controls, two test cartridges and their reagents**Steps:** Obtain controls from the freezer and allow them to thaw to room temperature. Label test cartridges. Run as a patient sample by adding reagents in order and 140uL control material to the proper cartridge. | **Material(s):** 500 uL TE buffer cryovial, Culturette swab. **Steps:** Dip a culturette swab in the TE buffer and swab wipe check areas. Break swab off into the cryovial using an orange barrier wipe. Process as patient sample. |
| **Xpert Factor II and Factor V** | MMQCI Control Panel (Cat. No. G109): 1) Normal/Wild Type (FII and FV Normal) 2) Heterozygous (FII and FV Heterozygous) 3) Mutant/Homozygous (FII and FV homozygous) | **Materials:** Control materials (varies, see Steps), testing cartridges**Steps:** Determine which control material will be used; rotate Heterozygous and Mutant/Normal. Allow controls to come to room temperature. Label cartridges. Vortex controls 10 seconds immediately before use. Inoculate labeled cartridges with the proper control material and run as patient specimens. Rotate modules.  | N/A |
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| **FilmArray Blood Culture Identification Panel2** | Positive and Negative Controls: MMQCI Filmarray BCID2 Control panel (Cat. No. M416) (fridge) | **Materials:** Positive and Negative controls, two test pouches **Steps:** Allow controls to come to room temperature. Vortex the tube for 10 seconds, quick spin to ensure no control media is left in cap. Inoculated labeled test pouches with the proper control and run as you would a patient sample.  | **Material(s):** 500uL sterile aliquot nuclease free water, Culturette Swab. **Steps:** Clean hood per molecular protocol. Set up loading block with appropriate materials. Soak swab for 1 minute in NFW and then swab wipe check areas. Break off swab directly into red sample injection vial, add buffer and test as patient sample. |
| **FilmArray Gastrointestinal Panel** | Positive Controls: MMQCI (Cat. No. M238) M2393718 and M2402818 (rotate between) (freezer)Negative Control: Cary Blair transport media | **Materials:** Positive and Negative controls, two test pouches**Steps:** Determine which positive control is needed, obtain from freezer and let thaw to room temperature. Vortex for 10 seconds and quick-spin to ensure no control media is left in the cap. Inoculate labeled test pouches with the proper control and run as you would a patient sample. |
| **FilmArray Respiratory Panel 2.1** | Microbiologics Positive and Negative QC material (Cat No. 8247) | **Materials:** Positive and Negative controls, UTM, two test pouches**Steps:** Hydrate each control vial with 300uL UTM. Vortex for 10 seconds and quick-spin to ensure no control media is left in the cap. Inoculate labeled test pouches with the proper control and run as you would a patient sample. |

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| **Interpretation/ Results** | * See individual Assay QC procedures.
* QC and wipe test results must be valid prior to reporting patient results.
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| **Method Performance Specifications** | * Adhere strictly to assay SOPs and QC/reagent storage guidelines.
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| **Result Reporting** | * Record QC results on inventory and QC logs.
* Record wipe testing results on wipe testing logs.
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| **References** | * GeneXpert and BioFire FilmArray Assay and Quality Control SOPs.
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| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Julie Laramie/Laura Schaefer | 12/13/2021 | Initial Version |
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