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| GeneXpert Factor II and Factor V Assay Quality Control |
| **Purpose** | This procedure provides instructions for Quality Control procedures required for the Xpert Factor II and Factor V Assay.  |
| **Policy Statements** | This procedure applies to all employees that work in molecular. |
| **Sample** | **New Lot/Shipment, 30 day Quality control, and Instrument Performance Verification after repairs:*** MMQCI Control Panel (Cat. No. G109)
* Normal – Wild Type – FII and FV Normal
* Heterozygous – FII and FV Heterozygous
* Mutant - Homozygous – FII and FV homozygous
* Previously tested patient sample (must have known results for BOTH FII and FV)

Run QC accordingly – rotating through heterozygous and homozygous samples: Rotate between [Options 1 or 2] **OR** [Options 3, 4, or 5] * Option 1: MMQCI Heterozygous FII & FV
* Option 2: One Previously tested patient sample – Heterozygous for FII **OR** FV
* Option 3: MMQCI Mutant (homozygous) FII & FV **AND** MMQCI Normal (Wild Type) FII & FV
* Option 4: Two Previously tested patient samples – Mutant (homozygous) for FII **AND** Normal (Wild Type) FII & FV
* Option 5: Two Previously tested patient samples – Mutant (homozygous) for FV **AND** Normal (Wild Type) FII & FV
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| Frequency | -Every 30 days: See IQCP 1.60-Receipt of new shipments-Receipt of new lots-After Xpert check or drastic system maintenance  |
| **Special Safety Precautions** | Molecular personnel are subject to occupational risks associated with specimen handling. Refer to the safety policies located in the safety section of the *Microbiology, Virology, and Molecular Procedure Manual:*1. [*Safety in the Microbiology/Virology 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)
2. [*Safe Work Practices in Molecular*](https://starnet.childrenshc.org/References/labsop/molbio/safety/mb-2.01-safe-work-practices-in-molecular.pdf)
* [*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)
* [*Biohazardous Spill in Molecular*](https://starnet.childrenshc.org/References/labsop/molbio/safety/mb-2.03-biohazardous-spills-in-molecular.pdf)
* [*Biohazard Containment*](https://starnet.childrenshc.org/References/labsop/index.php?view=folder&folder=molbio)
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| **Materials** |

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| Reagents | Supplies | Equipment |
| * MMQCI controls (G109)
* Previously tested patient samples
* 10% bleach
* 70% ethanol

Store MMQCI controls at 2-8°C until outdate on vial. Expire 30 days after opening.Store Patient Sample aliquots for QC at -70°C for 1 year  | * Xpert FII and FV kits
* 200 uL extended pipette tips
* Cartridge transfer tray

Store kits at 2-28°C. Kits are stable until the expiration date printed on the outer box.  | * Biosafety Hood
* Cepheid GeneXpert Instrument and computer
* Printer
* 200uL pipette
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| **Procedure** | **New Lot/Shipment and Monthly Quality control:**1. Clean hood and supplies: 10% bleach followed by 70% ethanol.
2. Change gloves.
3. Obtain the appropriate number of cartridges and Controls.

NOTE: Allow controls to come to room temp before use. 1. Label the cartridge(s).
2. For MMQCI controls:
3. Vortex for 5 – 10 seconds immediately before use
4. For Previously tested patient samples:
5. Invert the tube 5 – 10 times immediately before testing

OR1. If low volume: mix sample gently by pipetting up and down 5-10 times. Discard pipette tip after mixing and expelling all sample prior to testing.
2. Regardless of control type, process as a patient sample according to SOP MC 9.60 GeneXpert Factor II and Factor V Assay.
	* Rotate through modules.
	* Select “Positive Control 1” for anything other than a normal control.
	* Select “Negative Control 1” for normal control samples.
	* **NOTE:** Add what the QC run is for in the comments section (e.g. “30 day QC”, “New lot/New Ship QC”, etc.)
	* **NOTE:** Also comment on the sample type in the notes section (e.g. “Previous Normal Patient”, “MMQCI Heterozygous”, etc.)
3. Clean hood with 10% bleach followed by 70% ethanol.
4. Document QC in the GeneXpert Assay binder.

**NOTE:** Before reporting patient results, all controls must yield valid results.**Previously tested patient samples – Control Prep:** **NOTE:** samples must have known results for BOTH Factor II and Factor V1. Label 1.5 mL cryovials with control contents and expiration date (1 year from prep date).
2. Aliquot 100 uL into each cryovial and recap.
3. Label a cryobox lid and store at -70 °C.
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| **Interpretation and Documentation** | 1. Click on **View Results** on the top drop-down menu bar and select **View Test**.
2. Select the result you would like to review: Click **OK**.
3. Review result interpretations and amplification curves.
4. Click on the **Errors** tab to ensure no errors occurred during testing. (Section 9.18.2 in Operator Manual provides error code descriptions)
5. Record results in QC binder and file the report

**Reasons to retest with a new cartridge/troubleshooting:**1. An INVALID result:
	1. The sample was not properly processed.
	2. PCR was inhibited.
2. An ERROR result – the Probe Check control failed. This may indicate:
	1. The reaction tube was filled improperly.
	2. A reagent probe integrity problem was detected.
	3. The maximum pressure limit was exceeded.
	4. A valve positioning error was detected.
	5. IF the probe check passed, the error was caused by a system component failure
3. NO RESULT:
	1. This result indicated that insufficient data were collected (e.g. test stopped while in progress or power failure occurred).

**Valid Results:**MMQCI Controls (G109): 1. Normal – Wild Type – FII and FV Normal
2. Heterozygous – FII and FV Heterozygous
3. Mutant - Homozygous – FII and FV homozygous

Patient Controls: 1. Results match previous results for FII and FV testing

NOTE: If there is a QC failure, document observation and correction action. Report QC problems that cannot be resolved to the tech specialist. For repeated failures contact Cepheid Technical Support, the Technical Specialist and Technical Director.  Do not report patient results until problem is resolved.  |
| **References** | 1. Xpert Factor II and Factor V Package Insert, 301-0590, Rev B. Sunnyvale, CA: Cepheid; 2017.
2. Xpert FII & FV Genotype Panel G109, 8FEB12 v00. Scarbrough, ME: Maine Molecular Quality Controls, Inc.
3. GeneXpert Dx System Operatory Manual: Software Version 4.8, 3010045, Rev. K. Sunnyvale, CA: Cepheid; 2016.
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| **Historical Record** |  |  |  |  |
|  | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | Julie Laramie | 01/21/2020 | Initial Version |
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