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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

Test Heterozygous OR Normal and Homozygous (mutant) material on a rotating basis. **NOTE:** Controls are to be used until the manufacturer’s printed expiration date OR 8 months after opening, whichever date comes sooner.  |
| 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
* Household bleach
* 70% ethanol

Store MMQCI controls at 2-8°C until outdate on vial or up to 8 months.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:**Test Heterozygous OR Normal and Homozygous (mutant) material on a rotating basis. 1. Clean hood and supplies: 10% bleach dilution 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. Vortex 10 seconds immediately before use
3. 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.)
4. Clean hood with 10% bleach dilution followed by 70% ethanol.
5. Document QC in the GeneXpert Assay binder.

**NOTE:** Before reporting patient results, all controls must yield valid results. |
| **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

**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 |
| 2 | Julie Laramie | 12/06/2021 | Updated QC expiration date and removed use of patient samples |
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| **Archived by:** |  | **Archived Date:** |  |