GeneXpert
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Xpert® Factor II & Factor V

REF GXFIIFV-10

Cepheid

CE IVD

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Xpert® Factor II & Factor V

For *In Vitro* Diagnostic Use.

1 Proprietary Name

Xpert® FII & FV

2 Common or Usual Name

Xpert Factor II & Factor V Assay

Xpert Factor II & Factor V

3 Intended Use

The Xpert® Factor II & Factor V Assay is a qualitative *in vitro* diagnostic genotyping test for the detection of Factor II and Factor V alleles from sodium citrate or EDTA anticoagulated whole blood. The test is performed on the Cepheid GeneXpert® Dx System software version 4.0 or higher. This test is intended to provide results for Factor II (G20210A) and Factor V Leiden (G1691A) mutations as an aid in the diagnosis in individuals with suspected thrombophilia.

4 Summary and Explanation

The association of Factor II (G20210A) and Factor V Leiden (G1691A) mutations with an increased risk for venous thrombosis has been well documented.[1, 2, 3, 4] The Factor II or Prothrombin (G20210A) mutation refers to the G to A transition at nucleotide 20210 in the 3' untranslated region of the gene and is associated with increased plasma levels of prothrombin. Factor V Leiden (G1691A) refers to the G to A transition at nucleotide position 1691 of the Factor V gene, resulting in the substitution of the amino acid arginine by glutamine in the Factor V protein, causing resistance to cleavage by Activated Protein C (APC).

Factor II (G20210A) and Factor V Leiden (G1691A) mutations are present in 2% and 5% of the general population, respectively.[7]

5 Principle of the Procedure

The GeneXpert Dx System automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in whole blood using real-time Polymerase Chain Reaction (PCR) assays. The system consists of an instrument, personal computer, handheld barcode scanner, and preloaded software for running tests and viewing the results. The system requires the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is eliminated. For a full description of the system, see the *GeneXpert Dx System Operator Manual.*

The Xpert Factor II & Factor V Assay includes reagents for the detection of Factor II and Factor V normal and mutant alleles from sodium citrate or EDTA anticoagulated whole blood. Each assay cartridge also contains a Probe Check Control (PCC) that verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability.

The primers and probes in the Xpert Factor II & Factor V Assay determine the genotype of the Factor II gene (at position 20210) and/or the Factor V gene (at position 1691).

6 Reagents

6.1 Materials Provided

The Xpert Factor II & Factor V Assay kit contains sufficient reagents to process 10 specimens or quality control samples.

The kit contains the following:

Xpert Factor II & Factor V Assay Cartridges with integrated reaction tubes	**10**
Bead 1 and Bead 2 (freeze-dried)	**1 of each per cartridge**
Reagent 1	**3.0 mL per cartridge**
Reagent 2 (Guanidinium Hydrochloride)	**3.0 mL per cartridge**
CD	**1 per kit**

- Assay Definition Files (ADF)
- Instructions to import ADF into GeneXpert software
- Instructions for Use (Package Insert)

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

7 Storage and Handling

- Store the Xpert Factor II & Factor V Assay cartridges and reagents at 2 – 28 °C.
- Do not use cartridges that have passed the expiration date.
- Do not open a cartridge until you are ready to perform testing.
- Use the cartridge and reagents within 30 minutes after opening the cartridge lid.

8 Materials Required but Not Provided

- GeneXpert Dx System (catalog number varies by configuration): GeneXpert instrument, computer, barcode scanner and *GeneXpert Dx System Operator Manual.*

Note The GeneXpert Dx System catalog number varies by configuration. Contact Cepheid for the desired configuration and corresponding catalog number.

- GeneXpert Dx System: Software version 4.0 or higher.
- Pipette to dispense 50 µL sodium citrate or EDTA anticoagulated blood with aerosol-resistant filter tips.
- HemosIL FII & FV DNA Control, P/N 0020003500.

9 Warnings and Precautions

- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention[5] and the Clinical and Laboratory Standards Institute[6].
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Use the cartridges before the expiration date indicated on the kit.
- Do not open the Xpert Factor II & Factor V Assay cartridge lid except when adding sample.
- Do not use a cartridge that has been dropped or shaken after you have added the sample.
- Do not use a cartridge that has a damaged (e.g., bent or broken) reaction tube.
- Each single-use Xpert Factor II & Factor V Assay cartridge is used to process one test. Do not reuse spent cartridges.
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.
- Store the Xpert Factor II & Factor V Assay kit at 2-28 °C.
- Do not open a cartridge lid until you are ready to perform testing.
- In the event the internal pressure rises above the pre-set manufacturer limit, the run will automatically abort and an **ERROR** result will be reported.

10 Chemical Hazards[8, 9]

- UN GHS Hazard Pictogram:

- Signal Word: WARNING
- **UN GHS Hazard Statements**
  - May be harmful if swallowed
  - Causes skin irritation
  - Causes serious eye irritation
- **UN GHS Precautionary Statements**
  - **Prevention**
    - Wash thoroughly after handling.
    - Wear protective gloves/protective clothing/eye protection/face protection
  - **Response**
    - IF ON SKIN: Wash with plenty of soap and water.
    - Specific treatment, see supplemental first aid information.
    - If skin irritation occurs: Get medical advice/attention
    - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
    - If eye irritation persists: Get medical advice/attention
    - Call a POISON CENTER or doctor/physician if you feel unwell.

11 Specimen Collection, Transport, and Storage

To obtain adequate specimen, follow the instructions in this section closely.

- Only trained, licensed professionals should draw blood in EDTA or sodium citrate anticoagulant tubes.
- Do not centrifuge or concentrate the blood sample by plasma removal.
- Blood should be processed within 24 hours when stored at room temperature (22-28 °C). Samples should be stored at 2-8 °C if stored longer than 24 hours. Blood is stable up to 15 days when stored at 2-8 °C. The blood samples may also be stored at -20 °C or -80 °C for up to 3 months. Use of a freezer-compatible storage vial is recommended.

Note Allow frozen blood to thaw completely at room temperature. It is not recommended to freeze/thaw blood more than one time.

- Mix sample by inverting 5 times prior to dispensing into the cartridge

12 Procedure

12.1 Preparing the Cartridge

Important **Start the test within 15 minutes of adding the sample to the cartridge.**

To add the sample into the cartridge:

1. Remove the cartridge from the kit. It is not necessary to bring the cartridge to room temperature before use.
2. Mix sample by inverting the tube at least 5 times, until homogeneous.
3. Open the cartridge lid. Using a pipette with an aerosol resistant tip, transfer 50 µL of sodium citrate or EDTA anticoagulated blood to the bottom wall of the Sample opening of the Xpert Factor II & Factor V Assay cartridge. See Figure 1.
4. Close the cartridge lid.

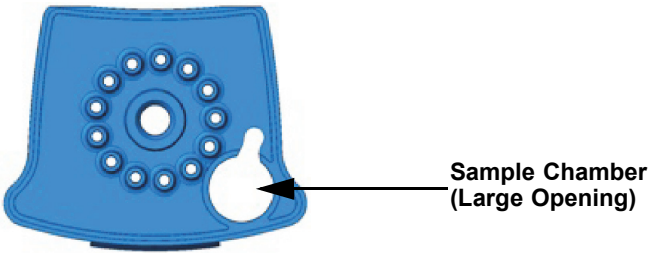

Figure 1. Xpert Factor II & Factor V Cartridge (Top View)

12.2 Starting the Test

Important **Before you start the test, make sure the Xpert FII, Xpert FV, and Xpert FII & FV Combo assay definition files are imported into the software. The assay definition files are on the supplied CD.**

This section lists the basic steps to run the assay. For detailed instructions, see the *GeneXpert Dx System Operator Manual.*

1. Turn on the GeneXpert Dx instrument and then turn on the computer. The GeneXpert software will launch automatically.
2. Log on to the GeneXpert Dx System software using your user name and password.
3. In the GeneXpert Dx System window, click **Create Test**. The Create Test window appears.
4. Scan barcode on cartridge.
5. In the Sample ID box, type the sample ID. Make sure you type the correct sample ID. Alternatively, scan the sample barcode. The sample ID is associated with the test results and is shown in the View Results window and all the reports.

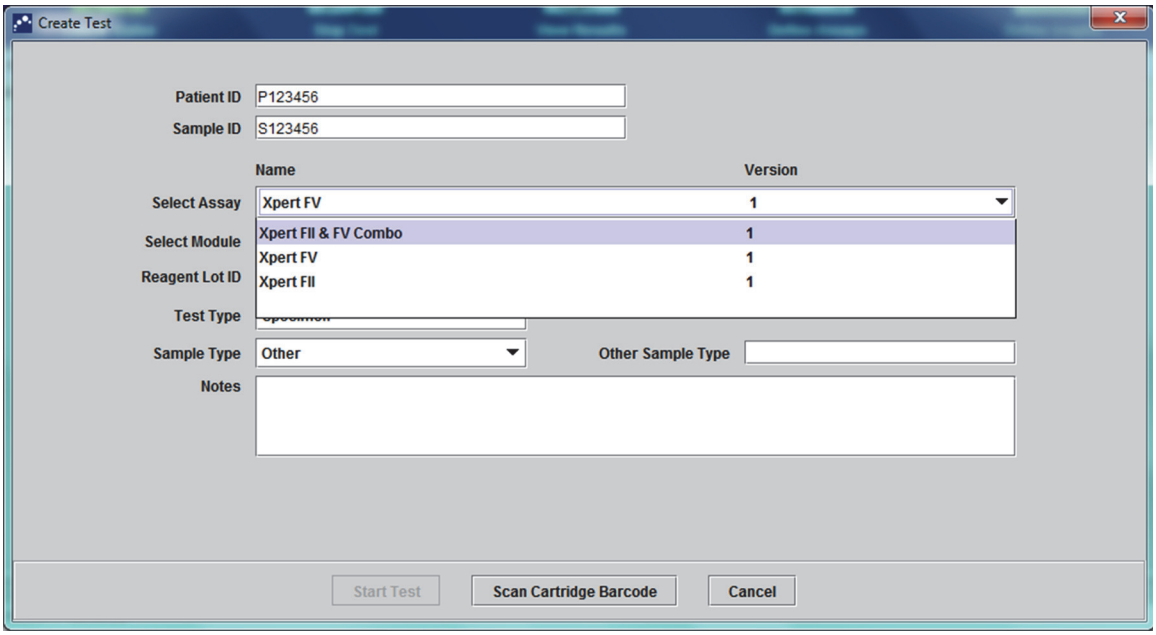

Figure 2. Create Test Window

6. From the **Select Assay** drop-down menu, select the appropriate assay to be run.
7. Click **Start Test**. In the dialog box that appears, type your password.
8. Open the instrument module door with the blinking green light and load the cartridge.
9. Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off.
10. When the system releases the door lock, open the module door and remove the cartridge.
11. Dispose of the used cartridges in the appropriate specimen waste containers, according to your institution's standard practices.

13 Viewing and Printing Results

For detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual*.

Note If reporting results using an LIS, confirm LIS results match system results for the patient ID; if results conflict, report the system results only.

14 Quality Control

CONTROL Each test includes a probe check (PCC).

Probe check control (PCC)-Before the start of the PCR reaction, the GeneXpert Dx System measures the fluorescence signal from the probes to monitor bead rehydration, reaction-tube filling, probe integrity and dye stability. Probe Check passes if it meets the assigned acceptance criteria.

External Controls - HemosIL FII & FV DNA Control P/N 0020003500 has been designed and validated for the External QC program of Xpert FII & FV Assay.

Alternatively, normal, heterozygous, or homozygous Factor II/Factor V whole blood samples (sodium citrate or EDTA anticoagulant) may also be used for training, proficiency testing, and external QC of the Xpert Factor II & Factor V Assay. Cell-based material is required. Do not use extracted DNA. External controls may be used in accordance with local, state, and federal accrediting organizations, as applicable.

15 Interpretation of Results

The results are interpreted by the GeneXpert Dx System from measured fluorescent signals and embedded algorithms to identify genotypes, and are shown in the following View Results windows:

For Xpert FII results when assay type FII is selected from the drop-down menu, see Figure 3 through Figure 5.

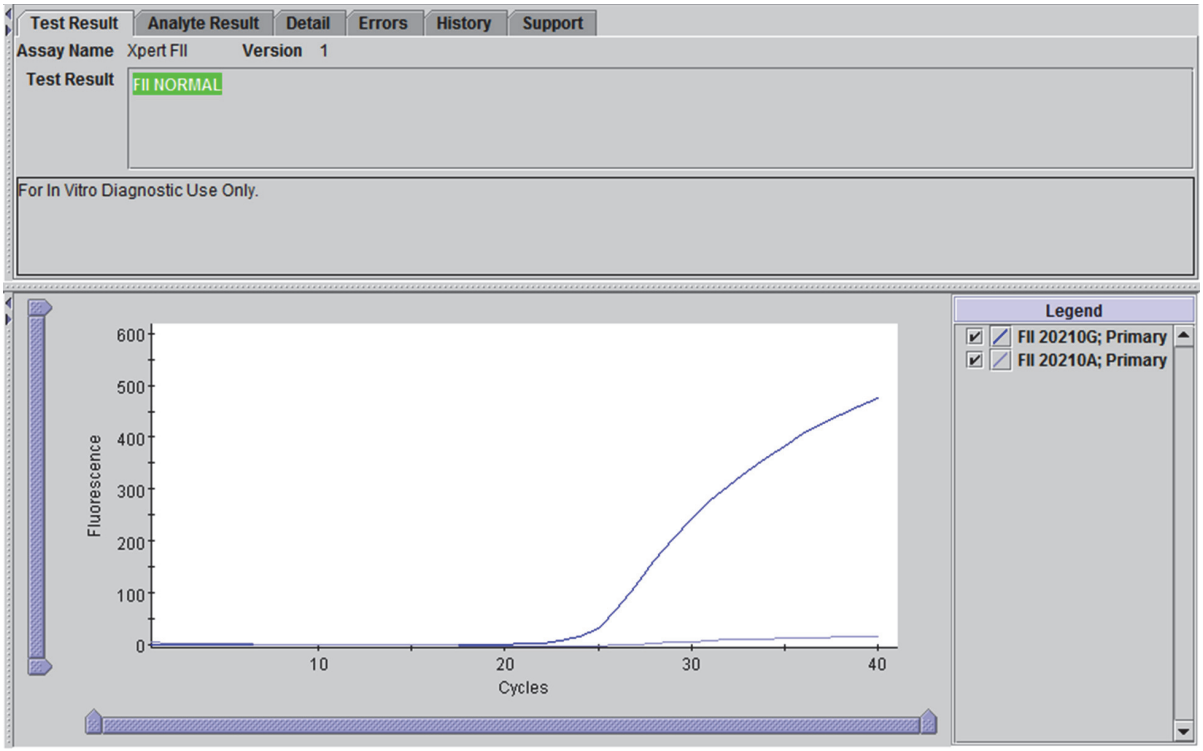

Figure 3. GeneXpert Dx System - View Results Window, Factor II Normal Result

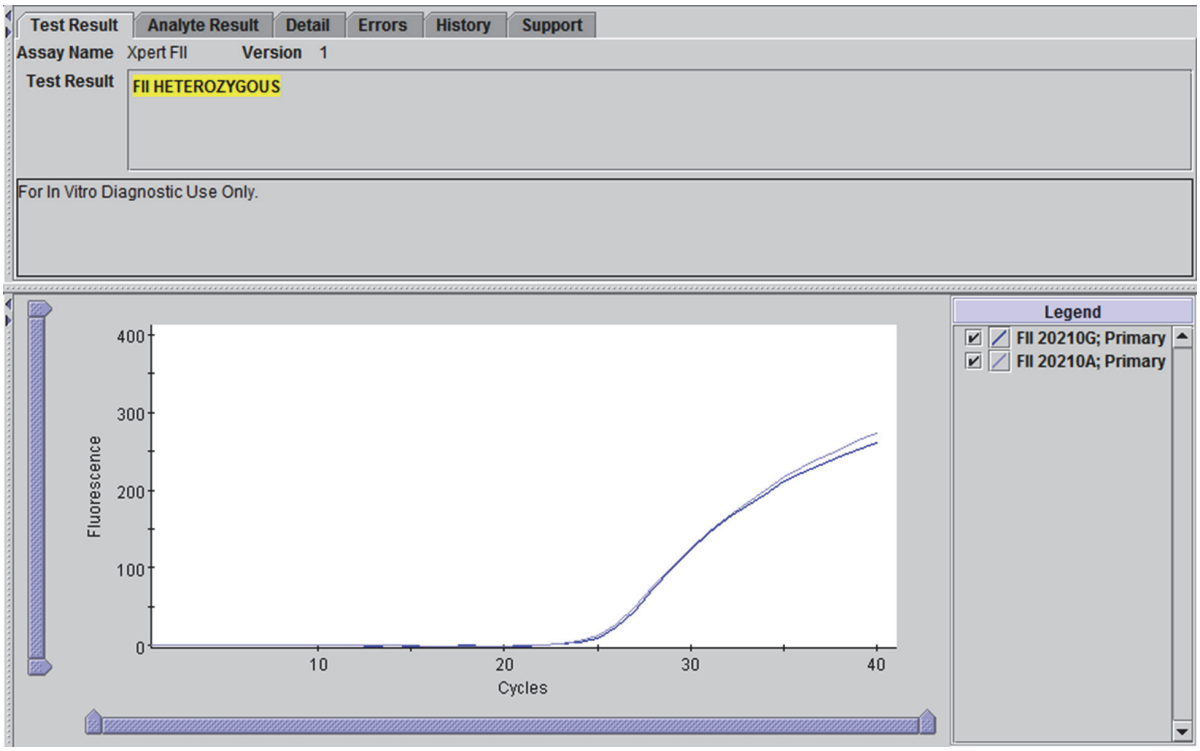

Figure 4. GeneXpert Dx System—View Results window, Factor II Heterozygous Result

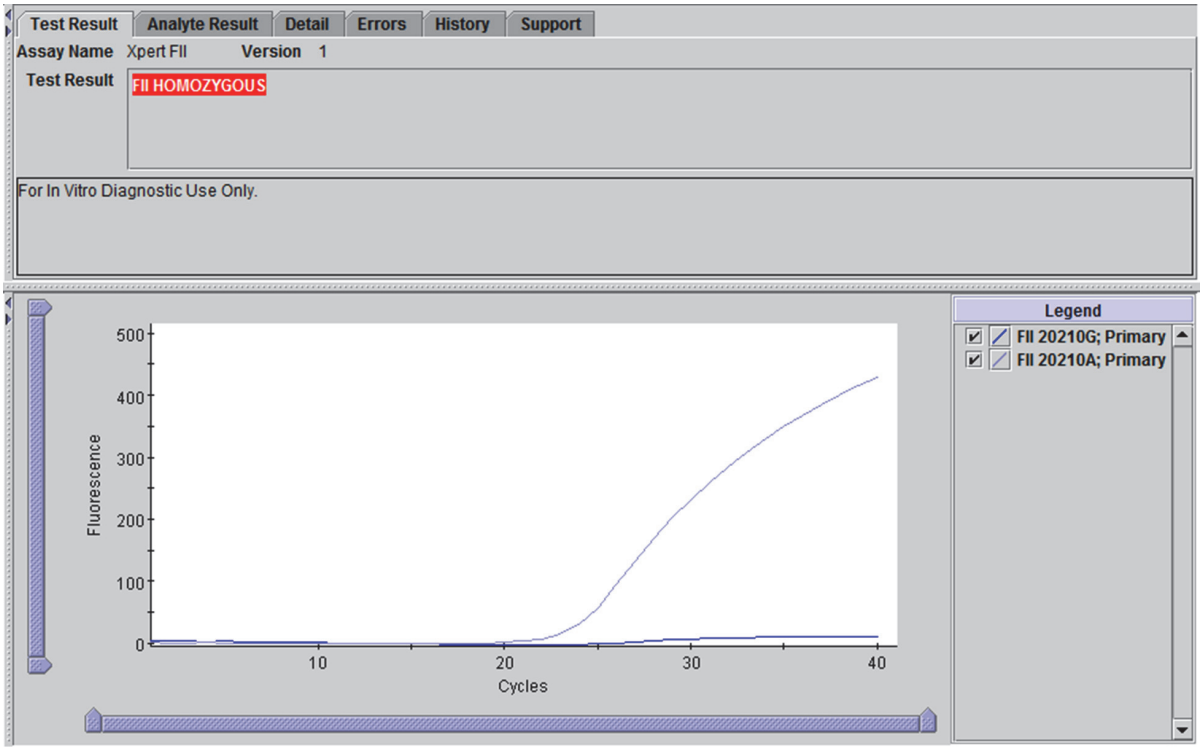

Figure 5. GeneXpert Dx System—View Results Window, Factor II Homozygous result

For Xpert FV results when assay type FV is selected from the drop-down menu, see Figure 6 through Figure 8.

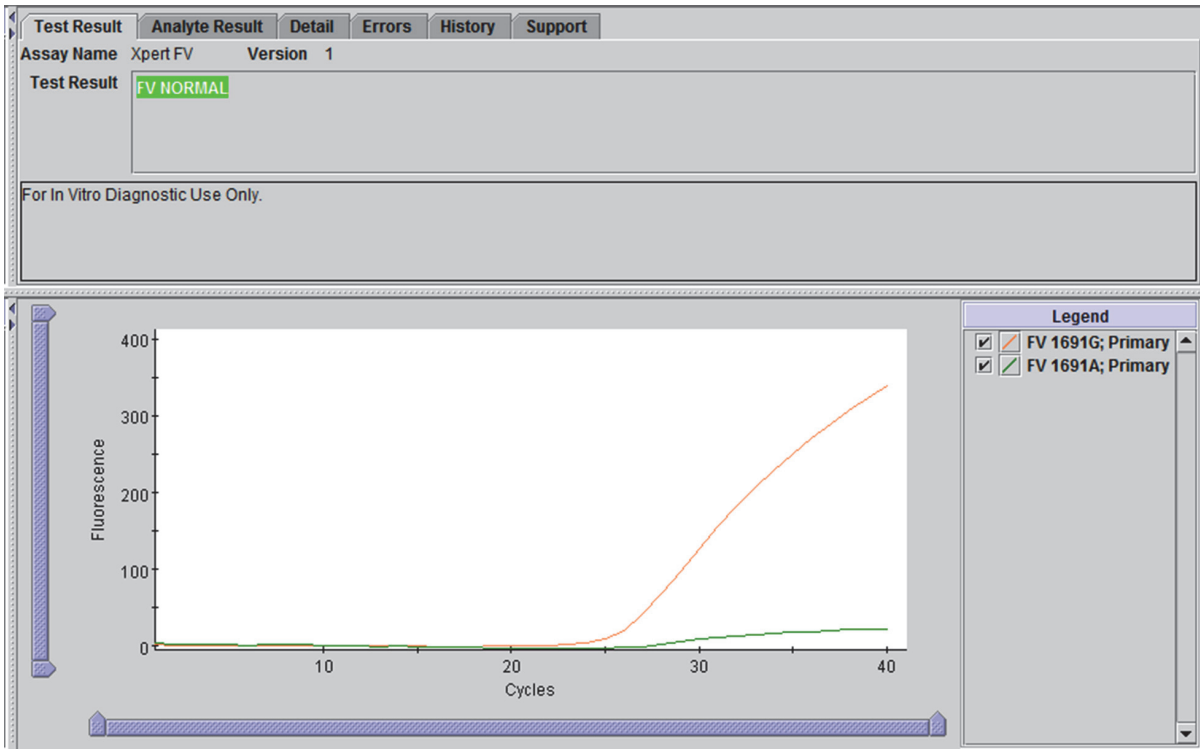

Figure 6. GeneXpert Dx System—View Results Window, Factor V Normal Result

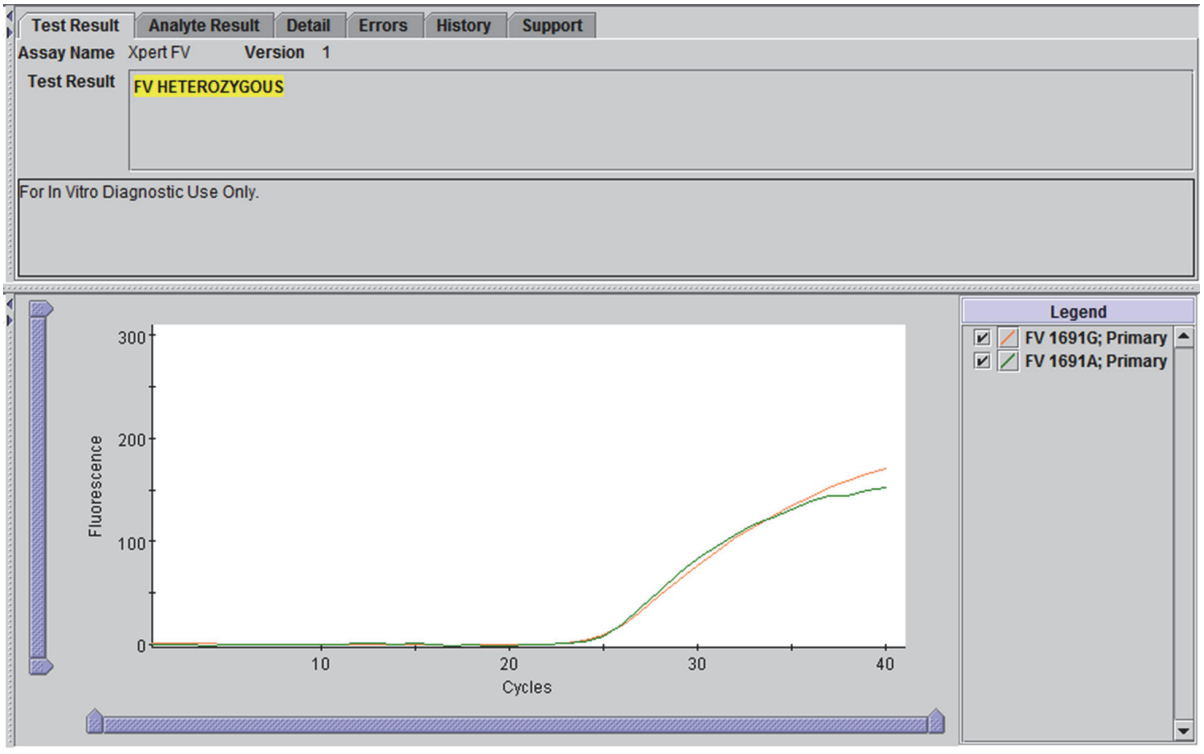

Figure 7. GeneXpert Dx System—View Results Window, Factor V Heterozygous Result

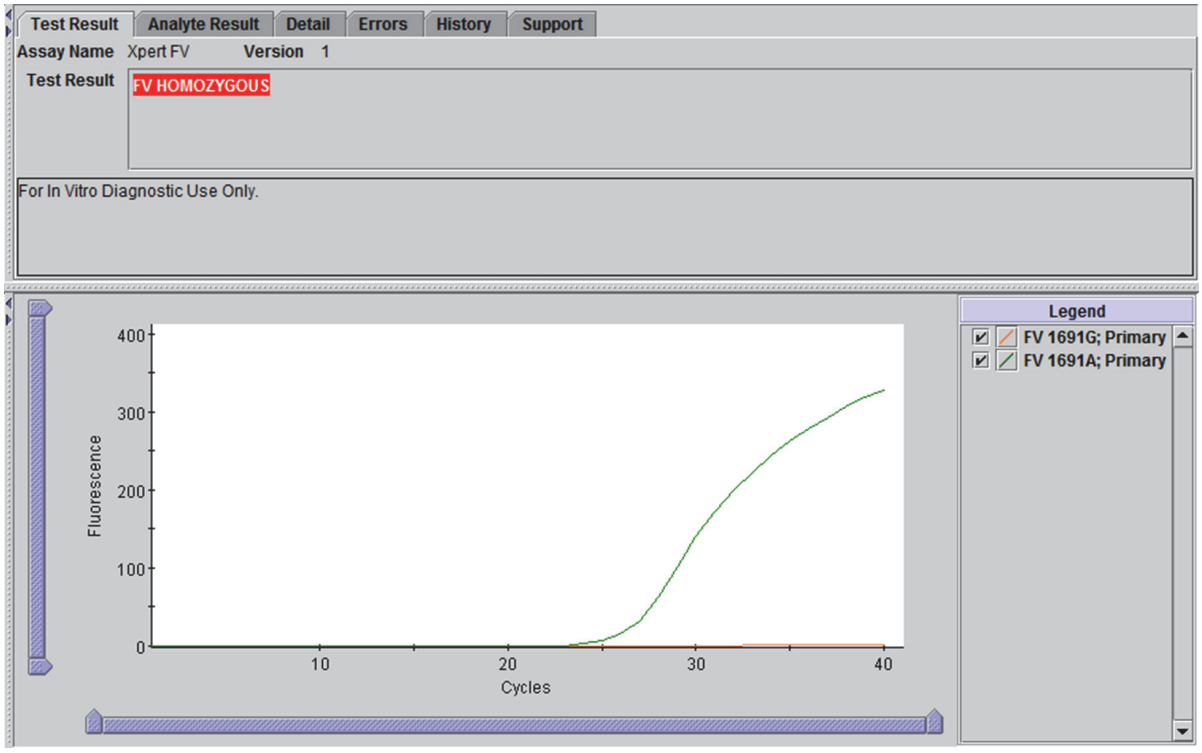

Figure 8. GeneXpert Dx System—View Results Window, Factor V Homozygous Result

For Xpert FII and FV results when assay type FII & FV Combo is selected from the drop-down menu, see Figure 9 through Figure 11.

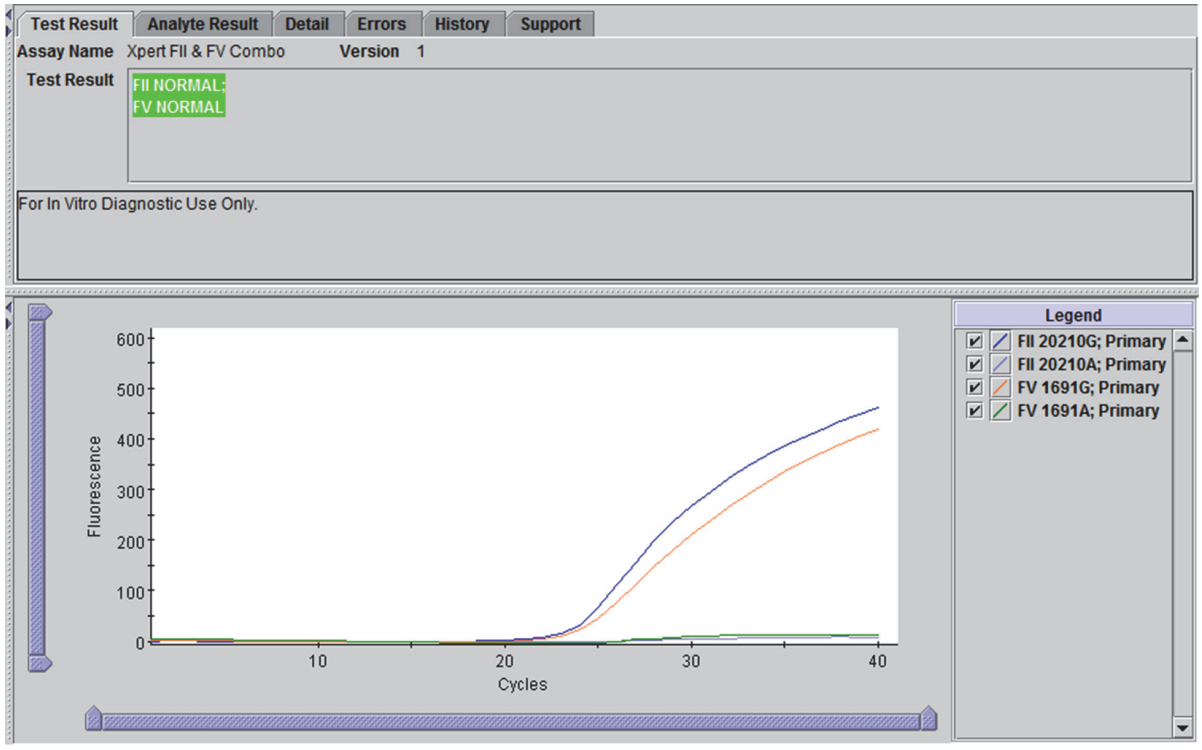

Figure 9. GeneXpert Dx System—View Results Window, FII & FV Normal Result

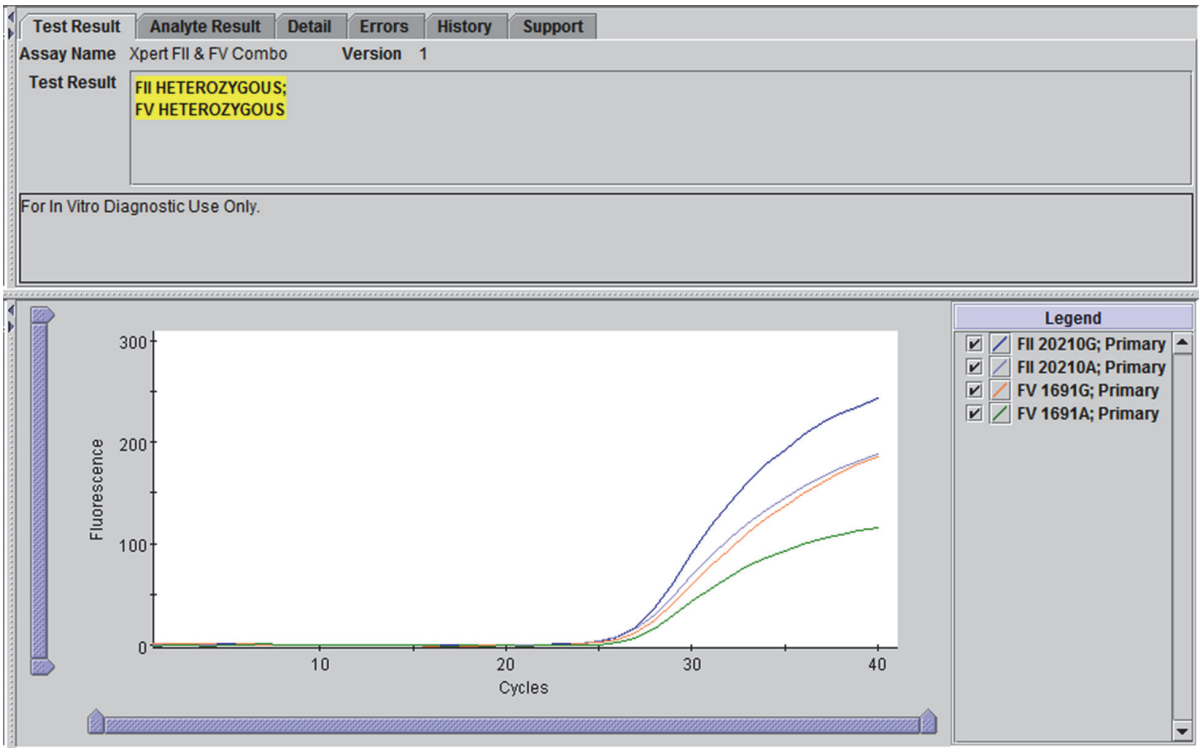

Figure 10. GeneXpert Dx System—View Results Window, FII & FV Heterozygous Result

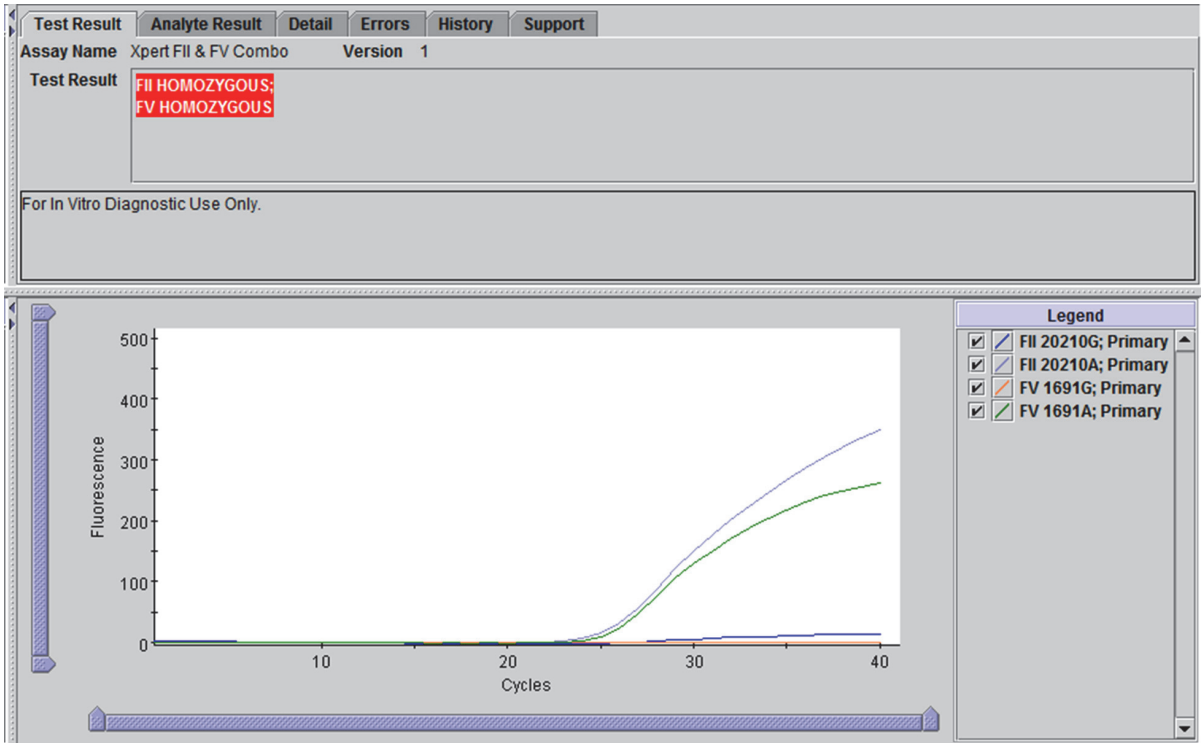

Figure 11. GeneXpert Dx System—View Results Window, FII & FV Homozygous Result

INVALID
Presence or absence of Factor II/Factor V normal and mutant alleles cannot be determined; repeat assay according to instructions below. The sample was not properly processed or PCR was inhibited.

- **INVALID**—Presence or absence of Factor II/Factor V normal and mutant alleles cannot be determined.
- Probe Check—PASS; all probe check results pass.

ERROR
Presence or absence of Factor II/Factor V normal and mutant alleles cannot be determined; repeat assay according to instructions below. The Probe Check control failed and the assay aborted possibly due to an improperly filled reaction tube, or a probe integrity problem was detected. Errors may also be caused by exceeding the maximum pressure limits or a system component failure.

- **ERROR**
- Probe Check—FAIL*; one or more of the probe check results fail.

*If the probe check passed, the error is caused by a system component failure.

NO RESULT
Presence or absence of Factor II/Factor V normal and mutant alleles cannot be determined; repeat assay according to instructions below. Insufficient data were collected to produce an assay result (for example, this can occur if the operator stopped a test that was in progress).

- **NO RESULT**
- Probe Check—NA (not applicable)

16 Reasons to Repeat the Assay

Repeat the assay using a new cartridge (do not re-use the cartridge) and a new aliquot of sodium citrate or EDTA anticoagulated whole blood:

- An **INVALID** result indicates that the sample was not properly processed or PCR was inhibited.
- An **ERROR** result indicates that the Probe Check control failed and the assay was aborted possibly due to an improperly filled reaction tube, or a reagent probe integrity problem was detected. Errors may also be caused by exceeding the maximum pressure limits or a system component failure.
- A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.

17 Limitations

- The performance of the Xpert Factor II & Factor V Assay was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test. Results from the Xpert Factor II & Factor V Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- Rare Factor V mutations (A1696G, G1689A, and A1692C) and any additional SNPs in the probe binding region may interfere with the target detection and yield an INVALID result.
- The performance of the Xpert Factor II & Factor V Assay has not been evaluated with samples from pediatric patients.

18 Interfering Substances

Patients on heparin therapy and blood transfusion patients may have blood specimens that potentially interfere with the PCR results and lead to invalid or erroneous results.

Studies of potentially interfering substances showed no inhibition from up to 14.3 USP units/mL heparin, 16 mg/dL bilirubin, 250 mg/dL added cholesterol, or 1932 mg/dL total triglycerides (lipids). No inhibition was observed using whole blood samples which had gone through one freeze-thaw cycle (hemolyzed blood). No statistical significance was observed between matched specimens drawn into EDTA or sodium citrate.

19 Expected Values

Factor II (G20210A) and Factor V Leiden (G1691A) mutations are present in 2% and 5% of the general population, respectively[7].

20 Performance Characteristics

20.1 Clinical Performance

Performance characteristics of the Xpert Factor II & Factor V Assay were determined in a multi-site investigational study at seven institutions by comparing the Xpert Factor II & Factor V Assay with bi-directional sequencing.

Specimens included those whose routine care called for collection of whole blood for Factor II and/or Factor V testing. Samples were first tested by routine methods used in each participating laboratory and then aliquots collected for study testing by the Xpert Factor II & Factor V Assay on the GeneXpert. Excess DNA was sent to a contract laboratory for bi-directional sequencing.

Performance of the Xpert Factor II & Factor V Assay was calculated relative to bi-directional sequencing results.

20.2 Overall Results

Xpert Factor II & Factor V Assay

A total of 1018 samples were tested for Factor II by both the Xpert Factor II & Factor V Assay and bi-directional sequencing. A total of 1014 samples were tested for Factor V by both the Xpert Factor II & Factor V Assay and bi-directional sequencing. To supplement the homozygous sample size, six human genomic DNA samples homozygous for Factor II and five homozygous for Factor V were also tested by the Xpert Factor II & Factor V Assay and bi-directional sequencing. The results are presented in Table 1.

The Xpert Factor II & Factor V Assay demonstrated a 99.3% overall accuracy relative to bi-directional sequencing for both Factor II and Factor V.

Table 1. Xpert Factor II & Factor V Assay Performance vs. Bi-directional Sequencing

Genotype	Number Tested	Number of Correct Calls on First Run	Number of Invalid[a] Calls on First Run	Agreement on First Run	Number of Correct Calls Including Repeat Run	Number of Invalid[a] Calls on Repeat Run	Agreement After Repeat Run
Factor II G20210A							
WT[d]	968	927	41	95.8%	963	5	99.5%
HET	50	48	2	96.0%	48	2	96.0%
HOM	7	7	0	100.0%	7	0	100%
Overall	1025[b]	982	43	95.8%	1018	7	99.3%
Factor V G1691A							
WT	895	860	35	96.1%	889	6	99.3%
HET	114	108	6	94.7%	113	1	99.1%
HOM	12	11	1	91.7%	12	0	100.0%
Overall	1021[c]	979	42	95.9%	1014	7	99.3%

a. No discordant results. Invalid results refer to “indeterminate” results
b. Bi-directional sequencing results for Factor II were not available for 4specimens
c. Bi-directional sequencing results for Factor V were not available for 8 specimens
d. WT (wildtype) is normal

Analytical Specificity

To evaluate the analytical specificity of the Xpert Factor II & Factor V Assay, normal gene sequences containing silent single nucleotide polymorphisms (SNPs) in the probe binding region as well as outside the probe binding region were synthesized. The presence of the additional SNP in the probe binding region, in most cases, resulted in an invalid result. When a valid result was obtained, it gave the correct genotype.

The presence of an additional SNP outside the probe binding region resulted in the correct genotyping call.

Analytical Sensitivity

Studies were performed to determine the minimum and maximum amount of input patient specimen for both EDTA and sodium citrate anticoagulated whole blood needed to obtain a correct genotype, such that the lower bound of the 95% confidence interval for the estimated "correct call" fraction is greater than 95%.

EDTA and sodium citrate anticoagulated blood samples were tested (n=20) at 8 volumes varying from 5 µL to 250 µL.

Although the assay can tolerate varying volumes from 15 µL - 100 µL, 50 µL is the recommended sample volume to minimize the risk of errors associated with limited and excess sample.

Reproducibility

A panel of 5 specimens, consisting of one of each specimen type listed below, was tested in duplicate by two different operators on 5 different days at each of three sites (3 specimens x 2 times/day x 2 operators per site x 5 days x 3 sites). One lot of Xpert Factor II & Factor V Assay kit was used at each of the 3 testing sites. Xpert Factor II & Factor V assays were performed according to the Xpert Factor II & Factor V procedure. Results are summarized in Table 2 through Table 5.

Study panel:

1. a sample with normal (wildtype) alleles for both Factor II & Factor V;
2. a sample heterozygous for Factor II mutation (i.e., one mutant and one wildtype allele for Factor II gene) and with normal (wildtype) alleles for Factor V;
3. a sample homozygous for Factor II mutation (i.e., two mutant alleles for Factor II gene) and with normal (wildtype) alleles for Factor V;
4. a sample with normal (wildtype) alleles for Factor II and homozygous for Factor V mutation (i.e., two mutant alleles for Factor V gene);
5. a sample with normal (wildtype) alleles for Factor II and heterozygous for Factor V mutation (i.e., one mutant and one wildtype allele for Factor V gene).

A summary of the results by site is shown in Table 2 and Table 3. There was no statistically significant difference in results among sites for either Factor II (p=1.000) or Factor V (p=1.000).

Table 2. Summary of Reproducibility Results by Site - Factor II

Specimen ID	Site 1	Site 2	Site 3	% Total Agreement by Sample
NOR	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II HET/Factor V NOR	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II HOM/Factor V NOR	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II NOR/Factor V HOM	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II NOR/Factor V HET	100% (20/20)	100% (20/20)	95.0% (19/20)[a]	98.3% (59/60)[a]
% Total Agreement by Site	100% (60/60)	100% (60/60)	98.3% (59/60)[a]	99.7% (299/300)[a]

a. No discordant results. One sample was indeterminate after retest.

Table 3. Summary of Reproducibility Results by Site - Factor V

Specimen ID	Site 1	Site 2	Site 3	% Total Agreement by Sample
NOR	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II HET/Factor V NOR	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II HOM/Factor V NOR	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II NOR/Factor V HOM	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
Factor II NOR/Factor V HET	100% (20/20)	100% (20/20)	95.0% (19/20)[a]	98.3% (59/60)[a]
% Total Agreement by Site	100% (60/60)	100% (60/60)	98.3% (59/60)[a]	99.7% (299/300)[a]

a. No discordant results. One sample was indeterminate after retest.

A summary of the results by operator is shown in Table 4 and Table 5. There was no statistically significant difference in results among sites for either Factor II (p=1.000) or Factor V (p=1.000).

Table 4. Summary of Reproducibility Results by Operator - Factor II

Specimen ID	Site 1		Site 2		Site 3		% Total Agreement by Sample
	Op 1	Op 2	Op 1	Op 2	Op 1	Op 2	
NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II HET/ Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II HOM/ Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II NOR/ Factor V HOM	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II NOR/ Factor V HET	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	90.0% (9/10)[a]	98.3% (59/60)[a]
% Total Agreement by Operator	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)	98.0% (49/50)[a]	99.7% (299/300)[a]

a. No discordant results. One sample was indeterminate after retest.

Table 5. Summary of Reproducibility Results by Operator - Factor V

Specimen ID	Site 1		Site 2		Site 3		% Total Agreement by Sample
	Op 1	Op 2	Op 1	Op 2	Op 1	Op 2	
NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II HET/ Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II HOM/ Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II NOR/ Factor V HOM	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (60/60)
Factor II NOR/ Factor V HET	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)	90.0% (9/10)[a]	98.3% (59/60)[a]
% Total Agreement by Operator	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)	100% (50/50)	98.0% (49/50)[a]	99.7% (299/300)[a]

a. No discordant results. One sample was indeterminate after retest.

To assess the between lot reproducibility, the 5-specimen panel described above was analyzed two times per day over 5 testing days using each of three assay lots at a single testing site (5 specimens x 2 runs per day x 3 lots x 5 days). A summary of the results by lot is shown in Table 6 and Table 7. There was no statistically significant difference in results between lots for either Factor II (p=1.000) or Factor V (p=1.000).

Table 6. Summary of Reproducibility Results by Lot - Factor II

Specimen ID	Lot 1	Lot 2	Lot 3	% Total Agreement by Sample
NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II HET/Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II HOM/Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II NOR/Factor V HOM	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II NOR/Factor V HET	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
% Total Agreement by Lot	100% (50/50)	100% (50/50)	100% (50/50)	100% (150/150)

Table 7. Summary of Reproducibility Results by Lot - Factor V

Specimen ID	Lot 1	Lot 2	Lot 3	% Total Agreement by Sample
NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II HET/Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II HOM/Factor V NOR	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II NOR/Factor V HOM	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
Factor II NOR/Factor V HET	100% (10/10)	100% (10/10)	100% (10/10)	100% (30/30)
% Total Agreement by Lot	100% (50/50)	100% (50/50)	100% (50/50)	100% (150/150)

21 References

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9. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).

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23 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

Region	Telephone	Email
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24 Table of Symbols

Symbol	Meaning
	Catalog number
	*In vitro* diagnostic medical device
	Do not reuse
	Batch code
	Consult instructions for use
	Caution
	Manufacturer
	Contains sufficient for <n> tests
	Control
	Expiration date
	CE marking – European Conformity
	Temperature limitation
	Biological risks

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