November 03, 2025

Roche Molecular Systems, Inc.
Nghia Luu
Regulatory Affairs Project Manager
4300 Hacienda Drive
Pleasanton, California 94588

Re: K252484
Trade/Device Name: cobas HCV
Regulation Number: 21 CFR 866.3170
Regulation Name: Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Tests
Regulatory Class: Class II
Product Code: MZP
Dated: August 6, 2025
Received: August 7, 2025

Dear Nghia Luu:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bhawna Poonia -S

for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252484

Device Name
cobas HCV

Indications for Use *(Describe)*
cobas HCV is an in vitro nucleic acid amplification test for both the detection and quantitation of hepatitis C virus (HCV) RNA, in human EDTA plasma or serum, of HCV antibody positive or HCV-infected individuals. Specimens containing HCV genotypes 1 to 6 are validated for detection and quantitation in the assay.
cobas HCV is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.
cobas HCV is intended for use as an aid in the management of HCV-infected patients undergoing anti-viral therapy. The assay can be used to measure HCV RNA levels at baseline, during treatment, at the end of treatment, and at the end of follow up of treatment to determine sustained or non-sustained viral response. The results must be interpreted within the context of all relevant clinical and laboratory findings.
cobas HCV has not been approved for use as a screening test for the presence of HCV in blood or blood products.
Assay performance characteristics have been established for individuals treated with certain direct-acting antiviral agents (DAA) regimens. No information is available on the assay's predictive value when other DAA combination therapies are used.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

cobas® HCV for use on the **cobas**® 5800/6800/8800 Systems
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Name	Roche Molecular Systems, Inc.
Address	4300 Hacienda Drive Pleasanton, CA 94588-2722
Contact	Nghia Luu Phone: (925) 366-0647 FAX: (925) 225-0207 Email: nghia.luu@roche.com
Date Prepared	August 6, 2025
Proprietary Name	**cobas**® HCV for use on the **cobas**® 5800/6800/8800 Systems
Common Name	**cobas**® HCV
Classification Name	ASSAY, HYBRIDIZATION AND/OR NUCLEIC ACID AMPLIFICATION FOR DETECTION OF HEPATITIS C RNA, HEPATITIS C VIRUS
Product Codes	MZP, 21 CFR 866.3170
Predicate Devices	**cobas**® HCV for use on the **cobas**® 5800/6800/8800 Systems (K221007)
Establishment Registration	Roche Molecular Systems, Inc. (2243471)

1. DEVICE DESCRIPTION

cobas® HCV is a quantitative test performed on the **cobas**® 5800 system, **cobas**® 6800 system and **cobas**® 8800 system. **cobas**® HCV enables the detection and quantitation of HCV RNA in EDTA plasma or serum of infected patients. Dual probes are used to detect and quantify, but not discriminate genotypes 1–6. The viral load is quantified against a non-HCV armored RNA quantitation standard (RNA-QS), which is introduced into each specimen during sample preparation. The RNA-QS also functions as an internal control to assess substantial failures during the sample preparation and PCR amplification processes. In addition, the test utilizes three external controls: a high titer positive, a low titer positive, and a negative control.

1.1. Principles of the Procedure

cobas® HCV is based on fully automated sample preparation (nucleic acid extraction and purification) followed by PCR amplification and detection. The **cobas**® 5800 system is designed as one integrated instrument. The **cobas**® 6800/8800 systems consist of the sample supply module, the transfer module, the processing module, and the analytic module. Automated data management is performed by the **cobas**® 5800 System or **cobas**® 6800/8800 Systems software(s) which assigns test results for all tests as target not detected, < LLoQ (lower limit of quantitation), > ULoQ (upper limit of quantitation) or HCV RNA detected, a value in the linear range LLoQ ≤ x ≤ ULoQ. Results can be reviewed directly on the system screen, exported, or printed as a report.

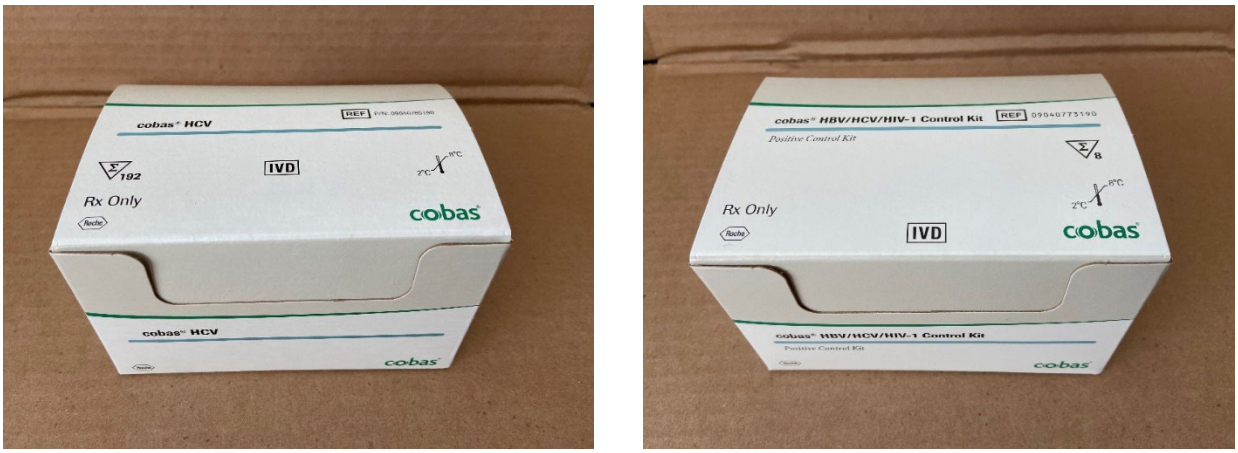
Nucleic acid from patient samples, external controls and added armored RNA-QS molecules are simultaneously extracted by addition of proteinase and lysis reagent to the sample. The released nucleic acid binds to the silica surface of the added magnetic glass particles. Unbound substances and impurities, such as denatured protein, cellular debris and potential PCR inhibitors are removed with subsequent wash buffer steps and purified nucleic acid is eluted from the magnetic glass particles with elution buffer at elevated temperature.

Selective amplification of target nucleic acid from the patient sample is achieved by the use of target virus-specific forward and reverse primers which are selected from highly conserved regions of HCV. Selective amplification of RNA-QS is achieved by the use of sequence-specific forward and reverse primers which are selected to have no homology with the HCV genome. A thermostable DNA polymerase enzyme is used for both reverse-transcription and PCR amplification. The target and RNA-QS sequences are amplified simultaneously utilizing a universal PCR amplification profile with predefined temperature steps and number of cycles. The master mix includes deoxyuridine triphosphate (dUTP), instead of deoxythimidine triphosphate (dTTP), which is incorporated into the newly synthesized DNA (amplicon).[1-3] Any contaminating amplicon from previous PCR runs are eliminated by the AmpErase enzyme, which is included in the PCR mix, during the first thermal cycling step. However, newly formed amplicon are not eliminated since the AmpErase enzyme is inactivated once exposed to temperatures above 55°C.

The **cobas**® HCV master mix contains dual detection probes specific for the HCV target sequences and one for the RNA-QS. The probes are labeled with target-specific fluorescent reporter dyes allowing simultaneous detection of HCV target and RNA-QS in two different

target channels.[4,5] When not bound to the target sequence, the fluorescent signal of the intact probe is suppressed by a quencher dye. During the PCR amplification step, hybridization of the probes to the specific single-stranded DNA template results in cleavage of the probe by the 5'-to-3' nuclease activity of the DNA polymerase resulting in separation of the reporter and quencher dyes and the generation of a fluorescent signal. With each PCR cycle, increasing amounts of cleaved probes are generated and the cumulative signal of the reporter dye increases concomitantly. Real-time detection and discrimination of PCR products is accomplished by measuring the fluorescence of the released reporter dyes for the viral targets and RNA-QS.

Figure 1: cobas® HCV for use on the cobas® 5800 System and cobas® 6800/8800 Systems



2. INDICATIONS FOR USE

cobas® HCV is an in vitro nucleic acid amplification test for both the detection and quantitation of hepatitis C virus (HCV) RNA, in human EDTA plasma or serum, of HCV antibody positive or HCV-infected individuals. Specimens containing HCV genotypes 1 to 6 are validated for detection and quantitation in the assay.

cobas® HCV is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.

cobas® HCV is intended for use as an aid in the management of HCV-infected patients undergoing anti-viral therapy. The assay can be used to measure HCV RNA levels at baseline,

during treatment, at the end of treatment, and at the end of follow up of treatment to determine sustained or non-sustained viral response. The results must be interpreted within the context of all relevant clinical and laboratory findings.

cobas® HCV has not been approved for use as a screening test for the presence of HCV in blood or blood products.

Assay performance characteristics have been established for individuals treated with certain direct-acting antiviral agents (DAA) regimens. No information is available on the assay's predictive value when other DAA combination therapies are used.

3. TECHNOLOGICAL CHARACTERISTICS

The primary technological characteristics and intended use of **cobas**® HCV are substantially equivalent to other legally marketed nucleic acid amplification test intended for the quantitative detection of hepatitis C virus. There are no changes to the assay reagents. New labeling for the assay has been included in this submission. This labeling contains revisions related to the use of the assay on the **cobas**® 5800/6800/8800 systems.

The technical characteristics of **cobas**® HCV are compared to the identified predicate device, **cobas**® HCV Quantitative nucleic acid test for use on the **cobas**® 5800/6800/8800 systems (K221007) in Table 1. The candidate device utilizes an updated analytical cycler with updated light source (Light Emitting Diode, LED) and Light Detection Digital Camera. Additionally, the **cobas**® 6800 system is updated to include two analytical cyclers compared to the predicate device. The system software has also been updated to version 2.0.

Table 1: Similarities and Differences between cobas® HCV and the Predicate Device

	Candidate Device: cobas® HCV	**Predicate Device: cobas® HCV (K221007)**
Proprietary Name	**cobas**® HCV Quantitative nucleic acid test for use on the **cobas**® 5800/6800/8800 systems	same
Regulation Number	21 CFR 866.3170	same
Regulation Name	ASSAY, HYBRIDIZATION AND/OR NUCLEIC ACID AMPLIFICATION FOR DETECTION OF HEPATITIS C RNA, HEPATITIS C VIRUS	same
Product Code	MZP	same

	Candidate Device: **cobas® HCV**	**Predicate Device:** **cobas® HCV (K221007)**
Intended Use	**cobas®** HCV is an in vitro nucleic acid amplification test for both the detection and quantitation of hepatitis C virus (HCV) RNA, in human EDTA plasma or serum, of HCV antibody positive or HCV-infected individuals. Specimens containing HCV genotypes 1 to 6 are validated for detection and quantitation in the assay. **cobas®** HCV is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection. **cobas®** HCV is intended for use as an aid in the management of HCV-infected patients undergoing anti-viral therapy. The assay can be used to measure HCV RNA levels at baseline, during treatment, at the end of treatment, and at the end of follow up of treatment to determine sustained or non-sustained viral response. The results must be interpreted within the context of all relevant clinical and laboratory findings. **cobas®** HCV has not been approved for use as a screening test for the presence of HCV in blood or blood products. Assay performance characteristics have been established for individuals treated with certain direct-acting antiviral agents (DAA) regimens. No information is available on the assay's predictive value when other DAA combination therapies are used.	same
Conditions for Use	For Prescription Use	same
Sample Types	Human EDTA Plasma, Serum	same
Analyte Targets	Hepatitis C RNA genotypes 1 to 6	same
Sample Preparation Procedure	Automated	same
Amplification Technology	Real Time PCR	same

	Candidate Device: cobas® HCV	Predicate Device: cobas® HCV (K221007)
Detection Chemistry	Dual detection probes labeled with target-specific fluorescent reporter dyes allowing simultaneous detection of HCV target and RNA-QS in two different target channels. Real time detection and discrimination of PCR products is accomplished by measuring the fluorescence of the released reporter dyes.	same
Controls Used	RNA-QS functions as an internal control. Three external controls: High Titer Positive, Low Titer Positive, Negative Control	same
Results Analysis	PCR cycle threshold analysis	same

4. NON-CLINICAL PERFORMANCE EVALUATION

4.1. System Equivalency Testing

The update of the analytic cycler with a different LED Source and light detection may potentially affect the Assay performance. To implement the commercially available **cobas**® HCV assay on the upgraded **cobas**® 6800/8800 systems, an assay migration approach was pursued following the FDA guidance for "*Assay Migration Studies for In Vitro Diagnostic Devices*" (April 25, 2013). Using this guidance, RMS determined that the existing clinical data provided in support of the original device approval is applicable in supporting the upgraded instrument. Therefore, only a selection of performance studies was executed to demonstrate equivalence of the two platforms by executing comparative studies on both the **cobas**® 6800/8800 systems 2.0 and the existing **cobas**® 6800/8800 (where applicable).

No changes have been made to the assay reagents.

Four non-clinical performance studies were completed with **cobas**® HCV to demonstrate system equivalency of **cobas**® 6800/8800 systems 2.0 to the current on-market **cobas**® 6800/8800 systems. Please note that the project name of the system modification to **cobas**® 6800/8800 systems 2.0 is an internal name and does not construe a device versioning nomenclature.

A summary of these studies are included in the sections 4.1.1 thru 4.1.4 below.

4.1.1. Analytical Sensitivity (Limit of Detection)

A comparison of results from testing at and around the expected LoD for **cobas**® HCV was completed using **cobas**® 6800/8800 systems 2.0 and **cobas**® 6800/8800 systems 1.4. A dilution series was prepared with five (5) concentration levels by diluting Roche HCV Secondary Standard, traceable to the 2nd WHO HCV International Standard in HCV negative pooled EDTA-plasma. The panels consisted of two (2) levels concentrated below the expected LoD, one (1) level concentrated near the expected LoD and two (2) levels concentrated above the expected LoD. A total of 66 replicates per concentration level and system were distributed across three (3) reagent lots, tested with three (3) **cobas**® 6800/8800 systems 2.0 and one (1) **cobas**® 6800/8800 systems 1.4 at one (1) external site, over the course of five (5) testing days.

The resulting data were analyzed to identify the Limit of Detection based on PROBIT Analysis and to determine the ≥ 95% positive reactive rate at the lowest target input level.

The difference between the $\log_{10}$ PROBIT concentration at 95% detection rate for the new **cobas**® 6800/8800 systems 2.0 and the **cobas**® 6800/8800 1.4 systems is within -0.2 to +0.2 $\log_{10}$ interval.

These results meet the Acceptance Criteria and demonstrate performance equivalency between the new **cobas**® 6800/8800 systems 2.0 and the **cobas**® 6800/8800 systems 1.4 for **cobas**® HCV in regards to Limit of Detection (LoD).

4.1.2. Linearity / LLoQ

A study to assess the linearity and LLoQ for **cobas**® HCV on **cobas**® 6800/8800 systems 2.0 was completed. In this study, HCV aRNA, HCV clinical material and HCV negative pooled EDTA-plasma were used to produce a dilution series consisting of sixteen (16) concentration levels, tested with three (3) kit lots, on six (6) testing days, and on three (3) **cobas**® 6800/8800 2.0 system. The resulting data were analyzed to identify the deviation from linearity according to CLSI guideline EP6-Ed2.

Two (2) separate dilution series were prepared to create sixteen (16) concentration levels by serially diluting HCV artificial stock material and high positive clinical material in pooled HCV negative EDTA-plasma. A total of thirty-six (36) replicates per concentration level, with sample input volume of 500 µL, were distributed across three (3) **cobas**® 6800/8800 systems 2.0 and three (3) **cobas**® HCV reagent kit lots. Dilutions and testing were performed at one (1) external

site over the course of six (6) testing days. Per day, three (3) runs, containing two (2) replicates per concentration level, were performed.

The results of the study have shown that, for all panel members with concentrations within the linear range, the absolute deviation for the linear regression was demonstrated to be equal to or less than ± 0.24 log10 for **cobas**® 6800/8800 systems 2.0, and therefore demonstrates performance equivalency between the new **cobas**® 6800/8800 systems 2.0 and the current on-market **cobas**® 6800/8800 systems 1.4 in regard to Linearity/LLoQ for **cobas**® HCV. No impact on the claimed LLoQ for **cobas**® HCV on the new **cobas**® 6800/8800 systems 2.0 was observed.

4.1.3. Precision

Precision was assessed by testing a panel consisting of seven (7) concentrations where three (3) levels were diluted from an HCV positive artificial stock material (aRNA) and four (4) levels were diluted from a high positive clinical specimen in HCV negative pooled EDTA-plasma. On twelve (12) testing days, two runs were completed each day with both one (1) **cobas**® 6800/8800 systems 2.0 instruments and one (1) **cobas**® 6800/8800 systems 1.4 instrument at one (1) external site. In each of the runs, three (3) replicates of the seven (7) panel members were tested. The study was conducted by using three (3) different reagent kit lots of **cobas**® HCV.

Two separate dilution series were prepared with seven (7) concentration levels by diluting HCV aRNA high positive material as well as clinical material in HCV negative pooled EDTA-plasma.

A total of 72 replicates per concentration level and system were distributed across three (3) **cobas**® HCV reagent lots, tested with one (1) **cobas**® 6800 system 2.0 and one (1) **cobas**® 8800 systems 1.4 at one (1) external site on twelve (12) testing days.

The Precision results for **cobas**® HCV on the **cobas**® 6800/8800 systems 2.0 and **cobas**® 6800/8800 systems 1.4 show the mean observed Log10 titer per panel member and the SD of all valid replicates per panel member and demonstrate performance equivalency between the new **cobas**® 6800/8800 systems 2.0 and the current on-market **cobas**® 6800/8800 Systems 1.4 in regards to Precision for **cobas**® HCV.

4.1.4. Method Comparison

The purpose of this study was to demonstrate equivalency between the **cobas**® 6800/8800 systems 2.0 and **cobas**® 6800/8800 systems 1.4 for the **cobas**® HCV in regard to Method Comparison.

155 archived, contrived or purchased anonymized, well-characterized clinical HCV positive specimens in EDTA plasma as well as 30 individual HCV negative single donor specimens were used to assess the performance equivalency in regard to Method Comparison.

The individual HCV positive specimens were diluted if necessary to achieve the sample size of ~ 50 well-characterized HCV positive plasma specimens between 1.5E+01 – 3.0E+03 IU/mL, ~ 50 specimens between 3.0E+03 – 5.0E+05 IU/mL and ~50 specimens between 5.0E+05 – 1.0E+08 IU/mL.

The individual HCV positive and individual HCV negative specimens were distributed across three (3) **cobas**® HCV kit lots and tested on three (3) **cobas**® 6800/8800 systems 2.0 as well as one (1) **cobas**® 6800/8800 systems 1.4. Testing was performed at one (1) external site over the course of five (5) working days.

The following methods of analyses were completed for this study in accordance with the CLSI EP-09c: Deming Regression Analysis, Systematic Bias Analysis, Allowable Total Difference and Negative Agreement Analysis.

Based on the results for the clinical acceptance criteria 100% of differences in viral load measurement between the **cobas**® 6800/8800 systems 2.0 and **cobas**® 6800/8800 systems 1.4 for positive samples were less than 0.5 $\log_{10}$ in viral concentration, and 100% of negative sample results agreed between **cobas**® 6800/8800 Systems 2.0 and **cobas**® 6800/8800 systems 1.4.

Performance equivalency between the new **cobas**® 6800/8800 systems 2.0 and the current on-market **cobas**® 6800/8800 systems 1.4 for **cobas**® HCV in regard to Method Comparison was demonstrated.

4.2. System Equivalency Testing Conclusion

All predefined clinical acceptance criteria were met for the Precision and Method Comparison studies. The LoD and Linearty/LLoQ studies met their acceptance criteria(s). Each of the four studies which covered LoD, Linearty/LLoQ, Precision, and Method Comparison supports the conclusion of substantial equivalence between **cobas**® HCV on the upgraded **cobas**® 6800/8800 systems and the current on-market **cobas**® 6800/8800 systems.

5. CLINICAL PERFORMANCE EVALUATION

5.1. System Equivalency

Equivalency of the **cobas**® HCV on the upgraded **cobas**® 6800/8800 systems and the current on-market **cobas**® 6800/8800 systems was demonstrated via performance studies and are summarized in the previous section on non-clinical performance evaluation.

6. CONCLUSIONS

No changes have been made to the assay reagents.

Four non-clinical performance studies were completed with **cobas**® HCV to demonstrate system equivalency of **cobas**® 6800/8800 systems 2.0 to the current on-market **cobas**® 6800/8800 systems. A comparison of the technological characteristics and conclusions drawn from nonclinical performance studies demonstrate that the device is as safe, as effective, substantially equivalent, and performs as well as the legally marketed predicate device identified above.

7. REFERENCES

1. Longo MC, Berninger MS, Hartley JL. Use of uracil DNA glycosylase to control carry-over contamination in polymerase chain reactions. Gene. 1990;93:125-8. PMID: 2227421.

2. Savva R, McAuley-Hecht K, Brown T, Pearl L. The structural basis of specific base-excision repair by uracil-DNA glycosylase. Nature. 1995;373:487-93. PMID: 7845459.

3. Mol CD, Arvai AS, Slupphaug G, et al. Crystal structure and mutational analysis of human uracil-DNA glycosylase: structural basis for specificity and catalysis. Cell. 1995;80:869-78. PMID: 7697717.

4. Heid CA, Stevens J, Livak KJ, Williams PM. Real time quantitative PCR. Genome Res. 1996;6:986-94. PMID: 8908518.

5. Higuchi R, Dollinger G, Walsh PS, Griffith R. Simultaneous amplification and detection of specific DNA sequences. Biotechnology (N Y). 1992;10:413-7. PMID: 1368485.