Bio QControl

P0139
HCV genotype panel for blood screening tests

RUO

REF P0139

The kit insert contains a detailed protocol and should be read carefully before testing the run control to ensure optimal performance

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Intended Use

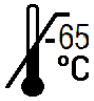
The HCV genotype panel for blood screening tests provides a panel of quantified HCV-RNA preparations covering a large proportion of the currently available genotypes. All members were quantified to obtain dilutions with the same concentration in copies/ml. It can be used to investigate genotype detection efficiency of molecular diagnostic test procedures on Hepatitis C virus RNA in blood samples. This product can be used with amplification methods, including (kinetic) TMA and real-time PCR assays and is useful for development and validation of nucleic acid test systems. It also can be used as a release panel for new batches of HCV-RNA test reagents. This product is not for diagnostic use and for research use only.

Key to Symbols Used

Manufacturer

Lot number

Catalogue number



Store below -65°C

Biological substance Category B

Research use only

Expiry date

Contents

Caution

Read instructions for use

Summary and Explanation

The HCV genotype panel for blood screening is designed for testing the analytical sensitivity or quantification limits of HCV-RNA tests. The panel helps ensure that procedures for HCV-RNA testing are properly validated, and that test results with an unknown group, genotype are consistent across manufacturers, testing laboratories, operators, platforms and assay formats. The bioQControl plasma HCV-RNA virus standards have been diluted in a pool of plasma units that tested negative for viral markers in individual donation NAT and serology testing. All viral standards were quantified by testing in the Siemens Versant bDNA 3.0 assays[1,2]. The viral concentrations in the plasma pool are ensured by gravimetrically recorded dilutions from calibrated viral stock solutions stored at –70°C.

HCV genotypes

In 2005 consensus for the classification of hepatitis C virus (HCV) was agreed[3]. The nomenclature for HCV variants and the criteria for their assignment into genotypes and subtypes was defined. An update is given to the previous nomemclature, incorporating additional sequence information, in May 2013[4]. Analysis resolved several nomenclature conflicts between genotype designations. Using consensus criteria a classification of HCV into seven confirmed genotypes, 67 subtypes and 20 provisionally geno, subtypes was created.

The variation was summarized and variants assigned as genotypes and subtypes in a consensus classification and nomenclature system and formal rules were agreed for the assignment and naming of future variants . Genotype and subtype assignments requires:

(1) one or more complete coding region sequence(s);
(2) at least three epidemiologically unrelated isolates;
(3) a phylogenetic group distinct from previously described sequences;
(4) exclusion of intergenotypic or intersubtypic recombination

Phylogenetic analysis of sequences containing >95% of the coding region reveals seven major phylogenetic groupings corresponding to genotypes 1-7. Based on the consensus criteria, confirmed subtypes (indicated by a letter following the genotype) require a complete or nearly complete coding region sequence differing from other sequences by at least 15% of nucleotide positions and sequence information.

Principles of the Evaluation Procedure.

The HCV genotype panel for blood screening members have been carefully formulated to mimic human plasma specimens containing 100 copies/ml (37 IU/ml) HCV-RNA. The HCV genotype panel for blood screening is suitable for evaluate the ability of the assay specific primers and probes to recognise most HCV genotypes. The composition of the panel covers world-wide most spread HCV-variants. As HCV is continuously evolving we recognise not all variants are included. Laboratories should find equal, positive responses for the different samples.

Traceability to 1st WHO standard for HCV-RNA.

A standard dilution of HCV-RNA genotype 1 preparation was included in the WHO collaborative study[5] to establish the 1st WHO standard for HCV-RNA and calibration study[6]. It was found one bDNA copy is equal to 2.73 IU of the first WHO HCV-RDNA standard. The other genotypes were calibrated on the genotype 1 preparation (sample 01). All panel members contain 37 IU/ml.

Composition P0139 HCV 100 copies/ml genotype panel for blood screening tests

Each panel member is quantified at 100 copies/ml# and filled off with 4.3 ml.

Table 1 composition of the panel

Member	HCV genotype	Country of origin
1	1	The Netherlands
2	2	The Netherlands
3	3	The Netherlands
4	4	The Netherlands
5	4	Egypt
6	4	Egypt
7	5	Germany
8	5	Germany
9	1a	USA
10	1a	USA
11	1a/1b	Lithuania
12	1b	Japan
13	1b	Japan
14	2a	Japan
15	2a	Japan
16	2b	Japan
17	2b	Japan
18	3a	Lithuania
19	3a	Lithuania
20	3a inact.	Lithuania
21	3b	USA
22	4c	USA
23	4e	USA
24	5a	USA
25	6a	USA
26	6a	USA
27	6n	USA
28	Negative	

The HCV-RNA standards has been diluted in a pool of plasma units that tested individually negative for HBsAg, anti-HBc, anti-HBs, anti-HCV, anti-HIV 1 and 2, HBV-DNA, HCV-RNA and HIV-1 RNA.

Storage Instructions

It is recommended to store the panel at –65°C or lower to ensure highest quality. Discard any unused material after the first use. Any panel members that appear cloudy or contain precipitates after thawing should be discarded.

Warning and precautions

The P0139 HCV genotype panel for blood screening tests members contain infectious HCV virions and are bio-hazardous. Observe the universal precautions for prevention of transmission of infectious agents when handling these materials[7,8,9]. Although the normal human plasma used in the production of this panel was negative for infectious disease markers the panel members should be handled as if capable of transmitting (unknown) infectious agents.

- Do not pipette by mouth.
- Use personal protective equipment, including lab coats, gloves and safety glasses.
- Do not eat, drink or smoke in areas where P0139 HCV genotype panel for blood screening tests and specimens are handled.
- Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution or equivalent.
- Dispose of all materials and liquids used in the procedure as if they contained pathogenic agents.

Test procedure

- Thaw the panel members quickly in a water bath at 37°C to avoid formation of cryo-precipitates.
- Mix gently during thawing until ice clot has disappeared.
- Immediately after thawing, vortex briefly, and give a short spin before releasing screw cap from the vials.
- The panel members should be handled and tested in a manner identical to that required for clinical specimens run in the test procedure being evaluated.
- Follow the manufacturers or testing laboratory instructions and recommendations for the handling and testing of clinical specimens.

Limitations

The P0139 HCV genotype panel for blood screening tests is not intended to replace the internal calibrators integral to in vitro diagnostic (IVD) test kits, but may be used as external, independent standards for the assessment of the performance of qualitative or quantitative NAT assays. The panel is not an in vitro diagnostic and for research use only.

References

1. Package insert Siemens Versant HBV-DNA bDNA 3.0 assay
2. Collins ML, Zayati C, Detmer JJ, Daly B, Kolberg JA, Cha TA, Irvine BD, Tucker J, Urdea MS Preparation and characterization of DNA standards for use in quantitative branched DNA hybridization assays. Anal Biochem. 1995 Mar 20;226(1):120-9
3. Simmonds P, Bukh J, Comber C, Deleage G, Enomoto N, Feinstone S, et al. Consensus proposals for a unified system of nomenclature of Hepatitis C virus genotypes . Hepatology 2005; 43: 962-973
4. Smith DB, Bukh J, Kuiken C, Scott Muerhoff AC, Rice CM, Stapleton JT, Simmonds P, Expansion Classification of Hepatitis C Virus into 7 genotypes and 67 subtypes; updated criteria and genotype assignment web resource. Hepatology 2014 Jan;59(1):318-27
5. Saldanha J, Lelie N, Establishment of the first international standard for nucleic acid amplification technology (NAT) assays for HCV RNA. WHO Collaborative Study Group. Heath A.Vox Sang. 1999;76(3):149-58
6. Saldanha J, Heath A, Lelie N, Pisani G, Nübling M, Yu M. Calibration of HCV working reagents for NAT assays against the HCV international standard. The Collaborative Study Group.Vox Sang. 2000;78(4):217-24
7. Centers for Disease Control (CDC). Recommendations for prevention of HBV transmission in health care settings. MMWR 1987; 36 (supplement no. 2S).
8. Centers for Disease Control (CDC). Update: Universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings. MMWR 1988; 37:377-388.
9. Centers for Disease Control (CDC). Guidelines for prevention of transmission of human immunodeficiency virus and hepatitis B virus to health-care and public-safety workers. MMWR 1989; 38(S-6): 1-36.

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