Guidance Manual

“Quality Control Evaluation of HCV Antibody Immunodiagnostic Kits”

NATIONAL INSTITUTE OF BIOLOGICALS
(Ministry Health & Family Welfare)
Government of India
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NOIDA-201307

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**FOREWORD**

Timely and accurate diagnosis is critical to the global efforts to prevent and treat infectious diseases. And yet, those on the front lines of this battle struggle to make do with inadequate and antiquated testing technology.

Immunodiagnostic tests, or immunoassays used for diagnostics, have been used extensively in any scientific disciplines and in many different ways. Such tests encompass any analytical method which uses antibodies as reagents, the results from which assist a diagnostic interpretation. The format of these tests has been equally varied; covering simple manual methods monitored by radioisotopes or enzymes; fully automated systems with integrated sophisticated detection; immunosensors; and 'dip-stick' tests.

The Immunodiagnostic Kit laboratory is notified as Central Drugs Laboratory (CDL) by Government of India vide Gazette No. 158, dated 27th August 2002 for *in-vitro* diagnostic devices for HIV, HCV and HBsAg. The laboratory has a Quality Management System in place and is NABL Accredited in accordance with the standard ISO/IEC 17025; 2005 in the field of biological testing. This ensures quality evaluation of diagnostic kits for safeguarding public health in the country.
**ABBREVIATIONS USED**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>DCG(I)</td>
<td>Drugs Controller General of India</td>
</tr>
<tr>
<td>ELISA</td>
<td>Enzyme Linked Immunosorbent Assay</td>
</tr>
<tr>
<td>FP</td>
<td>False Positive</td>
</tr>
<tr>
<td>FN</td>
<td>False Negative</td>
</tr>
<tr>
<td>HBV</td>
<td>Hepatitis B virus</td>
</tr>
<tr>
<td>HBsAg</td>
<td>Hepatitis B Surface Antigen</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C virus</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>ICT</td>
<td>Immuno Chromatographic Test</td>
</tr>
<tr>
<td>IRCS</td>
<td>Indian Red Cross Society</td>
</tr>
<tr>
<td>IDKL</td>
<td>Immuno Diagnostic Kit Laboratory</td>
</tr>
<tr>
<td>NSQ</td>
<td>Not of Standard Quality</td>
</tr>
<tr>
<td>NABL</td>
<td>National AccreditationBoardforTestingandCalibrationLaboratories</td>
</tr>
<tr>
<td>NIB</td>
<td>NationalInstituteof Biologicals</td>
</tr>
<tr>
<td>NIBSC</td>
<td>NationalInstituteof Biological Standards and Control</td>
</tr>
<tr>
<td>SQ</td>
<td>Standard quality</td>
</tr>
<tr>
<td>QA</td>
<td>QualityAssurance</td>
</tr>
<tr>
<td>QC</td>
<td>QualityControl</td>
</tr>
<tr>
<td>RT</td>
<td>RoomTemperature</td>
</tr>
<tr>
<td>SDP</td>
<td>Sample Deposition Plan</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard OperatingProcedure</td>
</tr>
<tr>
<td>SRRDU</td>
<td>SampleReceiptand Report Dispatch Unit</td>
</tr>
<tr>
<td>TP</td>
<td>True Positive</td>
</tr>
<tr>
<td>TN</td>
<td>True Negative</td>
</tr>
<tr>
<td>SP</td>
<td>Specificity</td>
</tr>
<tr>
<td>SN</td>
<td>Sensitivity</td>
</tr>
<tr>
<td>Ab</td>
<td>Antibody</td>
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## CONTRIBUTORS

**Immunodiagnostic Kit Lab**

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<th>Email</th>
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ACKNOWLEDGEMENT

The Immunodiagnostic Kit Laboratory staff express their profound gratitude and deep regards to Dr. Surinder Singh, Director i/c, NIB for his exemplary vision, guidance, continuous encouragement and unstinted support towards preparation of this document.

The hard work & committed efforts of all staff members towards laboratory strengthening is highly praiseworthy. On behalf of staff members, I sincerely acknowledge the immense help rendered by various Blood Banks of Delhi viz. Indian Red Cross Society and GTB Hospital, New Delhi etc. in preparing the in-house evaluation panels.

I hope the guidance manual will serve as a Reference Document to all stakeholders for successful implementation of quality system procedures.

Dr. Reba Chhabra
S-II &Lab. Head
Immunodiagnostic Kit lab.
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PURPOSE
The purpose of this guidance manual is to assist manufacturers of Diagnostics Kits, blood banks and transfusion services in developing a quality assurance (QA) program for Quality Control of Immunodiagnostic Kits which are routinely used for screening of blood donations and diagnosis of Infections in the laboratories, hospitals and blood banks. This would strengthen the Quality Control System of the diagnostic Industry and blood banks.

**SCOPE**

This guidance manual provides general information on procedures and practices for preparing plasma panels of optimal size and composition and Quality Control Evaluation of HCV Ab Simple/Rapid and ELISA diagnostic kits for the assessment of evaluation sensitivity and specificity parameters using a well characterized HCV Ab plasma panel and HCV Confirmatory kits in terms of band pattern corresponding to HCV viral proteins. The plasma panel members are tested with screening and confirmatory assays for HCV Ab and are also screened for HIV 1&2 Ab, HBsAg and Syphilis Ab to assign reactivity status for HCV Ab to the panel member. This guidance manual may be useful to diagnostic industry and blood banks in developing and administering a QA program. The methodology, specifications, and other terms referred to in this manual are intended to assist Diagnostic industry manufacturers and blood banks etc. in Quality Control of Immunodiagnostic Kits.
INTRODUCTION

National Institute of Biologicals is an autonomous institute under the Ministry of Health & Family Welfare set up for the quality assessment of biological products manufactured indigenously and imported in the country, works in coordination with the Regulatory Authorities such as Central Drugs Standard Control Organization (CDSCO) and the Indian Pharmacopoeia Commission.

The Immunodiagnostic Kit Laboratoryis notified as Central Drugs Laboratory (CDL) by Government of India vide Gazette No. G.F.R 601 E, dated 27th August 2002 for in-vitro diagnostic devices for HIV, HCV and HBsAg. Since 1997, the laboratory has been conducting Quality Control Evaluation of indigenously manufactured and imported kits (Rapid, ELISA and Confirmatory) for HCV Ab forwarded by Central Drugs Standard Control Organization (CDSCO) and procurement division of NACO. The Immunodiagnostic Kit Laboratory has a Quality Management System in place and is NABL accredited in accordance with the standard ISO/IEC 17025; 2005 in the field of biological testing.

Inviewtoimprovethethequalityofdiagnosticskits,thelst edition of Guidance Manual on “Quality Control Evaluation of Immunodiagnostic Kits” is developed by National Institute of Biologicals which can be used by the manufacturer of diagnostic Industry and Blood Bank Services to improve their quality control department. There are recommended methods provided to help the users to have consistent and reliable products in conformity with specific standards and hence to improve the quality of diagnostic kits. To ensure the better standard of diagnosis, it is essential that Industry and Blood bank services implement effective Quality Control testing of immunodiagnostic Kits.
SAMPLE RECEIVING

Kits for Quality Control Evaluation (QCE) of HIV, HCV, HBsAg are sent by DCG(I)/ADC(I)/port offices of CDSCO and received by Sample Receipt and Report Dispatch Unit (SRRDU) at NIB. Samples are then sent by SRRDU to Immunodiagnostic Lab for Quality Control evaluation.

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PROCEDURE FOR SAMPLE RECEIVING

1. On receiving the kit, check whether cold chain is maintained or not and then put the date of receiving on kit box.
2. Check the details of the kit mentioned in the SRRDU register, and details mentioned on the kit box label.
3. Accept the kits and sign the “Received by” column of SRRDU register.
4. Record the details of the kit received in Quality Evaluation of Biologicals Register (Proforma 1).
5. Store the kit as per the manufacturer’s instructions until use.
6. Any deficiencies noted regarding ‘sample submission’ is intimated to the SRRDU with the request to fulfill the requirement so that the laboratory can initiate testing.

QUALITY ASSURANCEOF IMMUNODIAGNOSTIC KITS

The primary function of immunodiagnostic investigations, as with any healthcare laboratory investigation, is to provide the clinician with analytical data obtained from examination of specimens submitted from patients and to assist in interpreting these results, in order to assist in diagnosis and control of therapy for the individual patient, for research or for public health purposes.

Quality assurance improves test reliability through helping to minimize the variability arising from biological or analytical sources, which is inherent in all quantitative measurements or qualitative examinations. Overall, quality assurance seeks to guarantee ‘the right result at the right time for the right investigation on the right specimen from the right patient, with result interpretation based on correct reference data’; to this may be added ‘at the right price’.

The evaluation of immunodiagnostic kits- Rapid, ELISA and confirmatory diagnostic kits is done with in-house reference plasma panel. Around 3000 plasma donor units have been collected from various blood banks of Delhi and other geographical locations. These have been aliquoted and characterized by testing with rapid and ELISA kits (based on different principles) and confirmatory assays (Western Blot and Line Immunoassay) for HIV, HCV, HBsAg and Syphilis. The panel members are stored at -20°C.
1. **Quality Control Evaluation** shall be based upon testing of sensitivity and specificity parameters, their acceptance criteria and interpretation.

2. **Validation of Tests**: Records of validation of individual tests shall be maintained in the laboratory.

3. **Equipment**: All the laboratory equipment used for quality control evaluation i.e., ELISA Reader, ELISA Washer and Biosafety Cabinet and temperature controlled equipment have been calibrated and put under AMC. In-house calibration of micro pipettes is done at regular intervals of six months.

4. **Verification of data**: The data compilation proformas are verified by the test performer. The “Evaluation Summary Sheet” shall be signed by the Analyst and approved by the Head of the laboratory.

5. **Presentation of Results**: The Certificate of Analysis shall mention the sensitivity and specificity values obtained and depending whether they meet with the respective specifications the results shall be designated as Standard Quality or Not of Standard Quality.

6. **Approval of the Certificate of Analysis**: Certificate of Analysis shall be signed by Analyst and the Head of Laboratory. Approval of the same shall be done by the Director, NIB.

7. **Turn around Time** for testing a batch of immunodiagnostic kit will be as given in the table below from the date of receipt of sample in the laboratory.

<table>
<thead>
<tr>
<th>TYPE OF TEST</th>
<th>TURN AROUND TIME (WORKING DAYS)</th>
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<tr>
<td>RAPID</td>
<td>20</td>
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<td>ELISA</td>
<td>28</td>
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<tr>
<td>CONFIRMATORY</td>
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INTERNATIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (EQAS)

Since 2000 the laboratory has been participating in International EQAS with CDC, Atlanta and for the past four years with National Serology Reference Laboratory, (NRL) Australia. The laboratory has enrolled in HIV, HBV, HCV and Syphilis serology EQAS with NRL Australia which is a NATA-accredited proficiency testing provider, complying with ILAC-G13:08/2007 and also is a World Health Organization (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HCV and other Blood-borne Infections. NIB was provided with a unique and confidential code number by NRL Australia.

In 2012, National Serology Reference Laboratory had distributed three (3) rounds of EQAS in the months of March, July and October. In each round of EQAS 10 coded samples each for HIV, HBV, HCV and Syphilis serology were received and tested. The results were uploaded electronically on Digital PT web site within the turn around time. The results were received electronically and they matched 100%. Certification of participation in EQAS 2011 from NRL, Australia has also been received by the laboratory.

SUPPLY OF HCV Ab REFERNCE PANELS

NIB has prepared HCV Antibody Plasma panel for supplying to indigenous manufacturers (having valid license) of Rapid/ ELISA Immunodiagnostic Kits.

HCV antibody – (NIB HCV Panel No.01/09) consists of 100 panel positive members and 300 negative members. The plasma members were characterized by using commercially available rapid, ELISA and confirmatory kits. The panel members were tested with EIA for HIV, HBsAg and syphilis.

The panel members are undiluted plasma specimens and are to be used only by indigenous kit manufacturers for in-house quality assessment of Rapid/ ELISA kits.

The use of panel was provided for the use of indigenous licensed immunodiagnostic kit manufacturers having:-

- Valid Manufacturing license
- Details of the number of batches produced in the last three years.
- Number of kits produced per batch.
- An undertaking that manufacturer will use the panel only for the purpose for which it has been provided and will not transfer part or whole panel to any other manufacturer or importer.
PROCEDURE FOR PREPARING HCV Ab PLASMA PANEL

Plasma panels of optimal size and composition are prepared for the evaluation of HCV Ab Simple/Rapid and ELISA diagnostic kits in terms of sensitivity and specificity parameters and Confirmatory kits in terms of band pattern corresponding to HCV viral proteins. The plasma panel members are tested with screening and confirmatory assays for HCV Ab and are also screened for HBsAg, HIV 1&/2 Ab and Syphilis Ab to assign reactivity status for HCV Ab to the panel member.

MATERIAL

Specimen

1. 1.8 ml vials of plasma samples

SCREENING AND CONFIRMATORY KITS ETC.

1. ELISA diagnostic kit for HCV Ab
2. Western Blot/ Line Immunoassay for confirming HCV Ab
3. ELISA diagnostic kit for HIV 1&/2 Ab
4. ELISA diagnostic kit for HBsAg
5. ELISA diagnostic kit for Syphilis Ab

PROCEDURE

1. Transfer coded 1.8ml vials containing plasma samples stored at -20°C to 4-8°C one day prior to testing.
2. On the day of testing bring plasma samples to room temperature half an hour prior to testing.
3. Screen each coded plasma sample on 2 different HCV ELISA assays either manually or with an automated system. Assign them reactive / non-reactive status as per the S/Co values (sample absorbance/ cut off).
4. Consider panel member as reactive if the S/Co value of the sample is > 1.
5. Consider panel member as non-reactive if the S/Co value of the sample is < 1.
6. Screen the reactive and non-reactive samples for other viral & bacterial markers viz HIV 1&/2 Ab, HBsAg and Syphilis Ab.
7. Confirm the HCV Ab reactive/non-reactive samples and also non-reactive samples for other viral & bacterial markers by confirmatory assay.
8. Consider the panel member as true HCV Ab negative if negative by HCV Ab ELISA and Confirmatory Assay (Western blot/ Line Immuno assay) and non-reactive for other viral & bacterial markers viz HIV 1&/2 Ab, HBsAg and Syphilis Ab.
9. Consider panel member as true HCV Ab positive if reactive by HCV ELISA and Confirmatory Assay (Western blot/ Line Immuno assay) and non-reactive by ELISA for other viral & bacterial markers viz. HBsAg, HIV 1&/2 Ab and Syphilis Ab.
10. Consider panel member as weak reactive if the S/Co value of the sample is >1 and < 2.0 and appearance of bands corresponding to HCV viral proteins (Core, NS3, NS4,NS5 and E2 env) by Western Blot/ Line Immuno assay.
11. Consider panel member as strong reactive if the S/Co value of the sample is > 2 and appearance of bands corresponding to HCV viral proteins (Core, NS3, NS4,NS5 and E2 env) by Western Blot/ Line Immuno assay.
12. Re-Characterize panels for HCV Ab once in a year by ELISA and record the results. If there is any change in the reactivity status the sample is not considered as a panel member.

**DOCUMENTATION**
Enter all the records of screening and confirmatory assays in the HCV Panel Characterization Records

**DESCRIPTION OF THE EVALUATION PANEL**
HCV evaluation panel prepared by NIB is composed of 581 naturally occurring, undiluted plasma samples out of which 100 panel members are positive for HCV antibody (strong reactive and weak reactive) and 481 panel members are negative for HCV antibody as per the table no. 1.

<table>
<thead>
<tr>
<th>Plasma Samples Positive for HCV Antibody and non-reactive for other viral markers</th>
<th>Plasma Samples Weak Reactive for HCV Antibody and non-reactive for other viral markers</th>
<th>Plasma Samples Negative for HCV Antibody and non-reactive for other viral markers</th>
</tr>
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<tbody>
<tr>
<td>99</td>
<td>1</td>
<td>481</td>
</tr>
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</table>

Total number: 581

**QC EVALUATION OF HCV ANTIBODY RAPID KITS**

**MATERIAL**

**Equipment**
1. Bio-safety Cabinet
2. Refrigerator
3. Vortex Mixer
4. MicroPipettes - Single channel (2-20 ul, 20-200 ul & 100-1000ul)
5. Incubator (37 degree C)

**Specimen**
1. Plasma panel members (Reactive and non-reactive)

**PLASTIC WARE**
1. Beaker
2. Cryobox
3. Cryovials (1.5ml, 1.8ml, 50 ml)
4. Zip lock bags
5. Measuring cylinder (100ml, 500ml)
6. Micropipette tips (20-200 ul, 1000ul)
7. Micropipette stand
8. Plastic Box (Bread Box)
9. Racks for cryovials
10. Storage boxes for tips
11. Storage box for cryovials
12. Microcentrifuge tubes

CHEMICALS/ REAGENTS- AR/GR GRADE

1. Ethanol absolute
2. Liquid Hand Wash Soap
3. Sodium Hypochlorite solution (4%)

MISCELLANEOUS

1. Aluminium Foil
2. Cotton
3. Gloves
4. Parafilm
5. Scissors
6. Filter Papers
7. Tissue Roll
8. Laboratory coats
9. Laboratory slippers

PROCEDURE FOR EVALUATION OF HCV ANTIBODY RAPID KITS

1. Test performer is given coded panel for monitoring their proficiency.
2. One test performer carries out the test.

Prepare work bench.

1. Spread 3-4 filter paper sheets (absorbent) on the work bench.
2. Place a plastic container filled ¾ with 1% freshly prepared sodium hypchlorite solution on the filter paper sheets and cover it with aluminium foil.
3. Keep single channel pipettes of various volumes 20ul-200ul and 100ul-1000ul capacity along with corresponding tip boxes on the filter paper sheets.
4. Keep marker pen, pair of scissors, 1% freshly prepared sodium hypochlorite swabs, 70% alcohol swabs, measuring cylinders, beakers on the spread sheet.
5. Wear a pair of gloves, and take out the required number of kit boxes from the cold room. Check the Lot Number & Expiry date of the kit. Place the kit boxes on the filter sheet and allow them to come to room temperature 30 min. prior to testing.
6. Take out the cryoboxes containing 1.8 ml aliquots of panel samples from the refrigerator. Place the cryoboxes on the filter paper sheet and allow the plasma samples to come to room temperature.
7. Take out the Rapid kits from Walk-in +4°C Cold Room 30 min. prior to testing.

Check functionality of equipment (if required).

1. Switch on the incubator, set it at required temperature observe it for 10 minutes till the set temperature is reached.
Panel members
1. Use plasma evaluation panel comprising of reactive and non reactive members

Sample deposition plan (SDP) and results record sheet (Proforma 3)
1. Seven number of SDP sheets (A-G) are prepared for simple/ rapid testing consisting of 90 samples per sheet from SDP A-F and 41HCV Ab samples for SDP G.
2. Keep the SDP sheet on the work bench to facilitate sample addition .
3. Prepare bench protocol of the test as per the manufacturer’s instructions indicating how a test is to be performed , the procedure of reagent preparation, sequence of the incubation timings, temperature and addition of reagents.

Performance of the test
1. Check and verify the kit boxes for the presence of the manufacturer’s seal.
2. Check visually for any damage in test device / strip / slide, leakage of reagents/ peeling off of the labels from the reagent vials. Record details in the kit evaluation proforma.
3. Record details in the kit evaluation proforma (Proforma 2)
4. Enter the Name of kit
5. Enter Name & address of manufacturer
6. Enter date of manufacture and date of expiry
7. Enter Lot/ Batch No.
8. Enter storage conditions
9. Enter whether seal on the it box is intact or not
10. Enter details of kit component, Lot no., expiry date for each components of the kit.
11. Enter date of testing
12. Enter room temperature at the time of testing
13. Record the details of centrifugation if panel members is turbid.
14. Enter name of performer

Assay Procedure
1. Perform test as per the manufacturer’s instructions given in the package / kit insert.
2. Take the required no. of test devices / strips / comb to be tested.
3. Tear off / cut the pouch and take out test devices / strips / comb / slides & write the panel sample ID number to be tested on the rapid test and place them on the spread filter sheet.
4. Add panel members into the device / strip /slide having the same ID no. of panel member.
5. Add reagents (if required).
6. Always run positive & negative controls.
7. Interpret the results as per the manufacturer’s instructions (Reactive / Non-reactive / Invalid).
8. Record the results in the preformatted results record sheets within the specified time period as per the kit insert.

Post test activity
1. Put back the panel sample box to its storageplace (2- 80°C) immediately after loading the sample into the wells of microtitre plate.
2. Discard the test device/strip/comb, tips and the reagent bottles into the plastic box filled three- fourth with 1% freshly prepared sodium hypochlorite, cover it with aluminium foil and leave it overnight.
3. Keep the label of the kit box having details eg. name of kit, lot No., date of manufacture, date of expiry, no. of tests and storage conditions in zip lock bag.
4. Wipe the used accessories (single channel pipettes, tip boxes, marker pens, forceps, and scissors) with 70% alcohol swabs.
5. Discard used alcohol and hypochlorite swabs in yellow color coded biohazardous bags.
6. Remove the soiled filtersheet from the work bench. Discard them in yellow color coded biohazardous bags.
7. Swab the work bench and put the pipetting devices and tip boxes back on to the respective shelves.
8. Disinfect with 70% alcohol swab all the instruments touch points, fridge handles etc.
9. Remove gloves and discard them in Biohazard container.
10. Wash hands, record and document the results.

**DOCUMENTATION**

1. Record the date on which the test is run; name of the kit; Lot/ batch No.; date of expiry; and temperature conditions etc. into the respective columns of the Kit Proforma (Proforma 2).
2. Record the results in the pre formatted HCV Ab Rapid results record sheet (Proforma 3). Three test performers record the observations of the results independently and countersign the record sheet. Two out of three test results determine the initial result.
3. The test performer enters the results of the evaluated test kit into the pre formatted data compilation proformas (Proforma 4). Compare the result of each panel member tested with the actual reactivity status of the panel member.
4. Record test result as True Positive (TP) if the Rapid test device/strip/comb/slide result is reactive with the known positive panel member.
5. Record test result as True Negative (TN) if the Rapid test device/strip/comb/slide result is negative with the known negative panel member.
6. Record test result as False Positive (FP) if the Rapid test device/strip/comb/slide result is reactive with known negative panel member.
7. Record test result as False Negative (FN) if the Rapid test device/strip/comb/slide result is non reactive with known positive panel member.
8. Re-test in duplicate if the result is in-valid, False Positive or False Negative using a new aliquot (stored at -20ºC) of the panel member. Two out of three test results determine the final result.
9. Make entry in the Quality Evaluation of Biologicals Register of the number of tests used, date of testing.
10. Count the number of TP, TN, FP and FN from the test results in the data compilation proforma.
11. Calculate sensitivity using the formula (TP/TP+FN) X100.
12. Calculate specificity using the formula (TN/TN+FP) X 100.
13. Sign the data compilation proforma and prepare evaluation summary sheet (Proforma 11).
14. Place all the kit insert, label of kit (in zip-lock bag), bench protocol, kit proforma, result record sheets and data compilation proforma in the file received from SRRDU.
15. Scientist Grade-III will prepare the “Certificate of Analysis” of the kit in terms of Standard Quality/ Not of Standard Quality in the format of the Sample Tracking System.
16. The testing file containing all the documents and test records along with “Certificate of Analysis” is then forwarded to the Lab Head for signature and onward transmission to the office of the Director.
17. The Sensitivity, Specificity values, Date of Dispatch of Evaluation Summary Sheet, File Number given by SRRDU and Analytical report number is entered in the Quality Evaluation of Biologicals Register by the test performer.
QC EVALUATION OF HCV ANTIBODY ELISA KITS

MATERIAL

Equipment

1. Bio-safety Cabinet
2. Deep Freezer –20° C
3. Refrigerator
4. Vortex Mixer
5. Incubator (37°C)
6. ELISA Washer
7. ELISA Reader
8. MicroPipettes - Single channel (2-20 ul, 20-200 ul & 100-1000ul) and Multi-channel (5-50 ul, 50-300ul)
9. Centrifuge

Specimen

1. Plasma samples

PLASTIC WARE

2. Beaker
3. Cryobox
4. Cryovials (1.5ml, 1.8ml, 50 ml)
5. Zip lock bags
6. Measuring cylinder (10ml, 25ml, 50ml, 100ml, 500ml)
7. Micropipette tips (20-200 ul, 1000ul)
8. Micropipette stand
9. Plastic Box (Bread Box)
10. Racks for cryovials
11. Storage boxes for tips
12. Reagent troughs
13. Storage box for cryovials

GLASSWARE

1. Beaker (50ml, 100ml, 500ml)
2. Measuring cylinders (10ml, 25ml, 50ml, 100ml, 500 ml)

CHEMICALS/ REAGENTS-AR/GR GRADE

1. Ethanol absolute
2. Liquid Hand Wash Soap
3. Sodium Hypochlorite
MISCELLANEOUS

1. Aluminium Foil
2. Cotton
3. Gloves
4. Marker pen
5. Scissors
6. Filter Papers
7. Tissue Roll
8. Plastic Forceps
9. Black plate covers
10. Laboratory coats
11. Laboratory slippers

PROCEDURE FOR ELISA
Test performer is given coded panel for monitoring their proficiency.
One test performer carries out the test.

Prepare work bench.
1. Spread 3-4 filter paper sheets (absorbent) on the work bench.
2. Place a plastic container filled ¾ with 1% freshly prepared sodium hypchlorite solution on the filter paper sheets and cover it with aluminium foil.
3. Keep single channel pipettes of various volumes 20ul- 200ul and 100ul- 1000ul capacity along with corresponding tip boxes on the filter paper sheets.
4. Keep marker pen, pair of scissors, 1% freshly prepared sodium hypochlorite swabs, 70% alcohol swabs, measuring cylinders, beakers on the spread sheet.
5. Wear a pair of gloves, and take out the required number of kit boxes from the cold room. Check the Lot Number & date of expiry of the kit. Place the kit boxes on the filter sheet and allow them to come to room temperature 30 min. prior to testing.
6. Take out the cryoboxes containing 1.8 ml aliquots of plasma samples to be used for either characterisation/QC evaluation from the refrigerator. Place the cryoboxes on the filter paper sheet and allow it to come to room temperature.
7. Take out the ELISA kits from Walk-in +4ºC Cold Room 30 min. prior to testing.

Check functionality of equipment
1. Switch on the incubator, set it at required temperature observe it for 10 minutes till the set temperature is reached.
2. Switch on the ELISA plate washer and run a programme of 2 cycles with reagent grade water (RO). Observe aspiration and dispensation. If any blockage is noticed, clean it with the help of washer pin.
3. Switch on the ELISA plate reader. Read a blank plate at required wavelength, to ensure whether the lamp is functional and the filters are in place.

Prepare Sample deposition plan (SDP) (Proforma 6)
1. The SDP sheet having details of the controls and the plasma samples to be characterized /takenup for QC evaluation is kept on the work bench to facilitate sample addition along with the bench protocol.

Prepare bench protocol by following the procedure of the test as per the manufacturer’s instructions, indicating how test is to be performed, procedure of reagent preparation,
sequence of the incubation timings, temperature and addition of reagents.

**Pre-assay procedures**

1. Check and verify the kit boxes for the presence of the manufacturer’s seal.
2. Verify the pH of the RO.
3. Check visually for any damage in microtiter plate, leakage of reagents/peeling off the labels from the reagent vials. Record details in the kit evaluation proforma.
4. Enter the name of kit
5. Enter the name & address of manufacturer
6. Enter the date of manufacture and date of expiry
7. Enter the kit Lot No.
8. Enter the kit storage conditions
9. Enter the condition of the kit box seal
10. Enter the details of kit component, with an entry of the Lot no., expiry, date for each of the kit components
11. Enter the date of Testing
12. Enter the room temperature at the time of testing
13. Enter the centrifuge details panel members (if turbid)
14. Enter the name of performer

**Assay Procedure**

1. Perform test as per the manufacturer’s instructions given in the package / kit insert.
2. Take the required no. of microtiter plate wells from the kit required for testing
3. Add positive, negative control and plasma panel members to the wells of microtiter plate as per the SDP sheet.
4. Add reagents in same order as mentioned in the Bench Protocol.
5. Interpret the results as per the manufacturer’s instructions.

**Post test assay activity**

1. Put back the panel sample box to its storageplace (2-8°C) immediately after loading the sample into the wells of microtitre plate.
2. Discard the microtiter plate, tips and the reagent bottles into the plastic box filled three-fourth with 1% freshly prepared sodium hypochlorite, cover it with aluminium foil and leave it overnight.
3. Keep the label of the kit box having details eg. name of kit, lot No., date of manufacture, date of expiry, no. of tests and storage conditions in zip lock bag.
4. Wipe all the used accessories (single channel pipettes, tip boxes, marker pens, forceps, and scissors) with 70% alcohol swabs.
5. Discard used alcohol and hypochlorite swabs in yellow color coded biohazardous bags.
6. Remove the soiled spread sheet from the work bench. Discard them in yellow color coded biohazardous bags.
7. Swab the work bench and put the pipetting devices and tip boxes back on to the respective shelves.
8. Disinfect with 70% alcohol swab all the instruments touch points, fridge handles etc.
9. Remove gloves and discard in Biohazard container.
10. Wash hands.

**DOCUMENTATION**
1. Record the date on which the test is run; name of the kit; Lot/batch No.; date of expiry; incubation timings and temperature conditions etc. into the respective columns of the Kit Proforma (Proforma 5).
2. Place the output of ELISA result in the evaluation file received from SRRDU. Using this output, proceed further with the calculations.
3. Check the O.D. values of blank and various kit controls to see whether they meet the validity criteria. If they do, then consider the run to be valid and calculate the Cut Off value and S/CO. If the validity criteria is not met the test run is in-valid and the test is repeated.
4. Compute the result of a valid run using EXCEL programme in the HCV Ab ELISA results record sheet (Proforma 7)
   a. ENTER S No.
   b. ENTER Sample ID
   c. ENTER Absorbance
   d. ENTER S/CO value
   e. ENTER Result (reactive or non reactive)
5. Consider the panel member reactive when the S/CO is 1 or more than 1, and is considered to be non reactive when the S/CO is less than 1.
6. The test performer enters the results of the evaluated test kit into the pre formatted data compilation proformas (Proforma 8). Compare the result of each panel member tested with the actual reactivity status of the panel member.
7. Record test result as True Positive (TP) if the ELISA test result is reactive with the known positive panel member.
8. Record test result as True Negative (TN) if the ELISA test result is non reactive with the known negative panel member.
9. Record test result as False Positive (FP) if the ELISA test result is reactive with known negative panel member.
10. Record test result as False Negative (FN) if the ELISA test result is non reactive with known positive panel member.
11. Re-test in-duplicate if the result is in-determinate, False Positive or False Negative using a new aliquot (stored at -20°C) of the panel member.
12. Count the number of TP, TN, FP and FN from the test results obtained in the data compilation proforma for every lot of the kit under evaluation.
13. Make entry in the Quality Evaluation of Biologicals Register of the number of tests used, date of testing.
14. Calculate sensitivity using the formula (TP/TP+FN) X100.
15. Calculate specificity using the formula (TN/TN+FP) X 100. Sign the data compilation proforma and prepare evaluation summary sheet (Proforma 11).
16. Place all the kit insert, label of kit (in zip-lock bag), bench protocol, kit proforma, result record sheets and data compilation proforma in the file received from SRRDU.
17. Scientist Grade-III will prepare the “Certificate of Analysis” of the kit in terms of Standard Quality/ Not of Standard Quality in the format of the Sample Tracking System.
18. The testing file containing all the documents and test records along with “Certificate of Analysis” is then forwarded to the Lab Head for signature and onward transmission to the office of the Director.
19. The Sensitivity, Specificity values, Date of Dispatch of Evaluation Summary Sheet, File Number given by SRRDU and Analytical report number is entered in the Quality Evaluation of Biologicals Register by the test performer.
QUALITY CONTROL (QC) EVALUATION OF HCV ANTIBODY CONFIRMATORY (WESTERN BLOT AND LINE IMMUNO ASSAY)

MATERIAL

EQUIPMENT

1. Bio-safety Cabinet
2. Deep Freezer –20° C
3. Refrigerator
4. Vortex Mixer
5. Rotary Shaker
6. Vacuum Pump
7. MicroPipettes - Single channel (2-20 ul, 20-200 ul & 100-1000ul) and Multi-channel (5-50 ul, 50-300ul)
9. Centrifuge

SPECIMEN

1. Plasma panel samples

CONFIRMATORY KITS HIV Ab

1. Western Blot
2. Line Immuno assay
3. Reverse Immuno Blot Assay

PLASTIC WARE

1. Beaker
2. Cryobox
3. Cryovials (1.5ml, 1.8ml, 50 ml)
4. Zip lock bags
5. Measuring cylinder (10ml, 25ml, 50ml, 100ml, 500ml)
6. Micropipette tips (20-200 ul, 1000ul)
7. Micropipette stand
8. Plastic Box (Bread Box)
9. Racks for cryovials
11. Storage box for cryovials

GLASSWARE

1. Beaker (50ml, 100ml, 500ml)
2. Measuring cylinders (10ml, 25ml, 50ml, 100ml, 500 ml)

**CHEMICALS/ REAGENTS-AR/GR GRADE**

1. Ethanol absolute
2. Liquid Hand Wash Soap
3. Sodium Hypochlorite

**MISCELLANEOUS**

1. Aluminium Foil
2. Cotton
3. Gloves
4. Marker pen
5. Scissors
6. Filter Papers
7. Tissue Roll
8. Plastic Forceps
9. Laboratory coats
10. Laboratory slippers

**PROCEDURE**

1. Test performer is given coded panel for monitoring their proficiency.
2. One test performer carries out the test.

**Prepare work bench.**

1. Spread 3-4 filter paper sheets (absorbent) on the work bench.
2. Place a plastic container filled ¾ with 1% freshly prepared sodium hypchlorite solution on the filter paper sheets and cover it with aluminium foil.
3. Keep single channel pipettes of various volumes 20ul- 200ul and 100ul- 1000ul capacity along with corresponding tip boxes on the filter paper sheets.
4. Keep marker pen, pair of scissors, 1% freshly prepared sodium hypochlorite swabs, 70% alcohol swabs, measuring cylinders, beakers on the spread sheet.
5. Wear a pair of gloves, and take out the required number of kit boxes from the cold room. Check the Lot Number & Expiry date of the kit. Place the kit boxes on the filter sheet and allow them to come to room temperature 30 min. prior to testing.
6. Take out cryoboxes containing 1.8 ml aliquots of plasma panel samples to be Characterised/ for QC testing from the refrigerator. Place the cryoboxes on the filter paper sheet and allow it to come to room temperature.
7. Take out the Confirmatory test kit from Walk-in +4ºC Cold Room 30 min. prior to testing.
8. **Prepare bench protocol** by following the procedure of the test as per the manufacturer’s instructions, indicating how test is to be performed, procedure of reagent preparation, sequence of the incubation timings, temperature and addition of reagents.

**Check functionality of equipment.**

1. Switch on the millipore vaccum pump assembly. Check whether it aspirates under vaccum properly.
2. Switch on the orbital shaker, set it at the required speed.
3. Write on sample addition sheet the S.No, Strip no. and sample ID in the order in which the samples are to be added for testing.
Assay Procedure
1. Take the required no. of strips from the kit box.
2. Add positive, negative controls and panel members to the incubation tray containing the strip.
3. Add reagents / diluent /conjugate / substrate and stop solution as per the prepared Bench Protocol.
4. Wash the strips as per the Bench Protocol.
5. Transfer strips face up (using forceps) to a paper towel and let dry. Do not dry strips between paper towels or pat dry. Do not interpret results until strips are completely dry. Paste the strips on the result record sheet.
6. Interpret and score the results as per the manufacturer’s instructions by comparing the bands on the strips side by side in comparison with bands on the reference strip.

DOCUMENTATION
1. Record the date on which the test is run; the name of the kit used; Lot/ batch No.; date of expiry; incubation timings and temperature conditions etc. into the respective columns of the Kit Proforma (Proforma 9).
2. Place the result record sheet in the file. Using this output, proceed further with the interpretation.
3. Make entry in the Quality Evaluation of Biologicals Register of the number of tests used, date of testing.
4. Enter the results in the data compilation proforma obtained of the evaluated test kit with each designated panel member and compare it with the reactivity status of the panel member (Proforma 10).
5. Place the kit insert, label of kit (in zip-lock bag), bench protocol, kit proforma, result record sheets and data compilation proforma in the file received from SRRDU.
6. Prepare evaluation summary sheet (Proforma 12). Results are interpreted according to the band pattern corresponding to HCV viral proteins.
7. The Date of Dispatch of Evaluation Summary Sheet and File Number given by SRRDU is entered in the Quality Evaluation of Biologicals Register by the performer.
8. Scientist Grade-III will fill up the “Certificate of Analysis” of the kit in terms of performance characteristics in the format in the Sample Tracking Module.
9. Send file containing all the records of testing along with “Certificate of Analysis” to Lab Head and office of the Director.
10. Enter the records of the evaluation in the formatted table in the Quality Evaluation of Biologicals Register.
### Proforma 1

**QUALITY EVALUATION OF BIOLOGICALS**

**RECORD OF KITS RECEIVED FOR QUALITY EVALUATION**

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<th>QC Batch Ref. No.</th>
<th>Details of forwarding authority and Mfr./Supplier</th>
<th>Name of kit, Lot/Batch No. &amp; Date of expiry</th>
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Proforma 2

NATIONAL INSTITUTE OF BIOLOGICALS
IMMUNO DIAGNOSTIC KIT LABORATORY

KIT PROFORMA FOR RAPID TEST KIT FOR HCV Ab

1. Name of the Kit :  
2. Type of Test : RAPID  
3. Principle of the Assay :  
4. Type of Antigen :  
5. Manufacturer :  
6. LOT # /Batch # :  
7. Date of Expiry :  
8. No of Tests/Kit :  
9. Kit received : Complete/Incomplete  
10. Temperature on receipt : Cold chain maintained

Details of the Kit Component

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Name of Performer:  
Signature:  
Date:
Proforma 3

NATIONAL INSTITUTE OF BIOLOGICALS
IMMUNO DIAGNOSTIC KIT LABORATORY

HCV Ab Rapid Test SDP & Result Record Sheet

KIT EVALUATED:  
ASSAY: RAPID  
MANUFACTURER:  
LOT / BATCH NO:  

Date of Testing:  
R. T. °C  
EXPIRY:  

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NAME OF PERFORMER  
COUNTER CHECKED BY

Guidance Manual: Quality Control of HCV Ab Immunodiagnostic Kits
Document ID No: NIB/IDKL/GM/02  
Effective Date:  
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## Proforma 4

### NATIONAL INSTITUTE OF BIOLOGICALS
### IMMUNO DIAGNOSTIC KIT LABORATORY

### HCV Ab RAPID TEST DATA COMPILATION SHEET

**KIT EVALUATED:**

**ASSAY:** RAPID

**MANUFACTURER:**

**LOT / BATCH NO.:**

### EXPIRY:

**Date of Testing:**

**R. T. °C**

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**TP:**

**TN:**

**FP:** ``

**FN:**

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**Guidance Manual:** Quality Control of HCV Ab Immunodiagnostic Kits

**Document ID No:** NIB/IDKL/GM/02

**Effective Date:** Page no. 29 of 43
Proforma 5

NATIONAL INSTITUTE OF BIOLOGICALS
IMMUNO DIAGNOSTIC KIT LABORATORY

KIT PROFORMA FOR ELISA / AUTOMATED ELISA

Name of kit:  
Manufacturer:  
Lot No:  

Test Date:  
RT:  
Exp. Date:  

Storage:  
Refrigerator/Cold room  
Temperature: 4 °C

Washer:  
Reader:  

Incubator/ temp:  
Operators:  

Cold chain : maintained  
Seal : intact  
Kit received : complete  
Reason for conducting test : For evaluation/ characterization

DETAILS OF KIT COMPONENT

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<th>REAGENTS</th>
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Sample Details: serum/ plasma, frozen/ 2-8°C, whether centrifuged,Y/ N  
If yes, g/ RPM_______  
Duration__________

Guidance Manual: Quality Control of HCV Ab Immunodiagnostic Kits  
Document ID No: NIB/IDKL/GM/02  
Effective Date:  
Page no. 30 of 43
## REAGENT PREPARATION

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**Cutoff Formula:**

**Remarks:**

**Name of Performer:**

**Signature:**

**Date:**
**Proforma 6**

NATIONAL INSTITUTE OF BIOLOGICALS  
IMMUNO DIAGNOSTIC KIT LABORATORY  

SAMPLE DEPOSITION PLAN (SDP) FOR ELISA  

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<th>KIT EVALUATED:</th>
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## HCV Ab ELISA Result Record Sheet

**NATIONAL INSTITUTE OF BIOLOGICALS**  
**IMMUNO DIAGNOSTIC KIT LABORATORY**

**KIT EVALUATED:**  
**ASSAY:** ELISA  
**MANUFACTURER:**  
**LOT / BATCH NO:**  
**Date of Testing:**  
**R. T. °C**

**EXPIRY:**

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**CUT OFF =**  

**SIGNATURE**
Proforma 8

NATIONAL INSTITUTE OF BIOLOGICALS
IMMUNO DIAGNOSTIC KIT LABORATORY

HCV Ab ELISA DATA COMPILATION SHEET

KIT EVALUATED:  
ASSAY:  ELISA
MANUFACTURER:  
LOT / BATCH NO:  

Date of Testing:  
R. T. °C

EXPIRY:

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TP:  
TN:  
FP:   
FN:  
Proforma 9

NATIONAL INSTITUTE OF BIOLOGICALS IMMUNO DIAGNOSTIC KIT LABORATORY

KIT PROFORMA FOR CONFIRMATORY ASSAY

Name of kit:  
Manufacturer:  
Lot No:  

Test Date:  
RT:  
Exp. Date:  

Storage:
Refrigerator/Cold room
Temperature: 

Operators: 

Cold chain : maintained
Seal : intact
Kit received : complete
Reason for conducting test : For evaluation/ characterization

Sample Details: serum/ plasma, frozen/2-8°C, whether centrifuged, Y/ N
If yes, g/ RPM_______
Duration________________

DETAILS OF KIT COMPONENT

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<tr>
<td>Substrate</td>
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<td>Wash buffer</td>
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Validity Criteria:

INTERPRETATION: Name of Performer:

REMARKS: Signature:

Date:
**Proforma 10**

NATIONAL INSTITUTE OF BIOLOGICALS

IMMUNO DIAGNOSTIC KIT LABORATORY
HCV Ab CONFIRMATORY ASSAY DATA COMPILATION SHEET

KIT EVALUATED:  
ASSAY: WESTERN BLOT/ LINE IMMUNO ASSAY  
MANUFACTURER:  
LOT / BATCH NO:  

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TP:  
TN:  
FP:  
FN:

**Date of Testing:**  
R. T. °C  
EXPIRY:

**Guidance Manual:** Quality Control of HCV Ab Immunodiagnostic Kits

**Document ID No:** NIB/IDKL/GM/02  
**Effective Date:**  
Page no. 38 of 43
**Proforma 11**

**NATIONAL INSTITUTE OF BIOLOGICALS**
**IMMUNO DIAGNOSTIC KIT LABORATORY**

**EVALUATION SUMMARY SHEET**

1. NAME OF THE KIT:
2. NAME OF THE MANUFACTURER:
3. FORWARDED BY:
4. LOT NO:
5. TYPE OF ASSAY:
6. MANUFACTURING DATE:
7. EXPIRY DATE:
8. RECEIPT DATE IN THE LAB:
9. NUMBER OF TESTS RECEIVED:
10. NUMBER OF TESTS PUT UP:
11. INTERPRETATION:
12. CALCULATION:
   NO. OF TRUE POSITIVE (TP):
   NO. OF TRUE NEGATIVE (TN):
   NO. OF FALSE POSITIVE (FP):
   NO. OF FALSE NEGATIVE (FN):

   A. SENSITIVITY: \((\frac{TP}{TP + FN}) \times 100\) =

   B. SPECIFICITY: \((\frac{TN}{TN + FP}) \times 100\) =

13. RESULTS:

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<th>Specifications (As per DCG(I) letter no: 26-1/Misc/2003-DC dated: 12.06.03)</th>
<th>Results Obtained</th>
<th>Remarks</th>
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<td>STANDARD QUALITY/ NOT OF STANDARD QUALITY</td>
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<td>Specificity</td>
<td>(\geq 98.0%)</td>
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**REMARKS: ………………….ELISA/ RAPID KIT; LOT NO: IS OF/ NOT OF STANDARD QUALITY.**

Signature of the Performer
Name & Designation
Date:

Signature of the Analyst
Name & Designation
Date:

---

**Guidance Manual:** Quality Control of HCV Ab Immunodiagnostic Kits  
**Document ID No:** NIB/IDKL/GM/02  
**Effective Date:**  
**Page no.:** 39 of 43
**Evaluation Summary Sheet**

1. **Name of the Kit:**
2. **Name of the Manufacturer:**
3. **Name of the Importer & Supplier:**
4. **Forwarded By:**
5. **Type of Assay:**
6. **Manufacturing Date:**
7. **Expiry Date:**
8. **Receipt Date in the Lab:**
9. **Number of Tests Received:**
10. **Number of Tests Put Up:**
11. **Assay Validity:**
   - Strong Reactive Control:
   - Weak Reactive Control:
   - Non-Reactives Control:
12. **Interpretation:**

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13. **Results:**

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**Remarks:**

Signature of the Analyst: 
Name & Designation: 
Date: 

Signature of the Lab. Head: 
Name & Designation: 
Date: 

Signature of the Analyst: 
Name & Designation: 
Date:
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REFERENCES


Note: Follow Manufacturer’s Instructions provided with kits used for screening and confirmatory assays.