## Anti-HCV

**Antibody to hepatitis C virus (anti-HCV)**

<table>
<thead>
<tr>
<th>REF</th>
<th>Σ</th>
</tr>
</thead>
<tbody>
<tr>
<td>03290352 119</td>
<td>100</td>
</tr>
</tbody>
</table>

### English

**Intended use**

Anti-HCV is an in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum or plasma. This assay is indicated as an aid in the diagnosis of infection with HCV. This assay may also be used to detect antibodies to HCV in serum and plasma specimens to screen donors of cells (excluding blood cells and derivatives), tissues and organs intended for transplantation. The Elecsys Anti-HCV is not intended for screening donors of blood and blood products.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

### Important Patent License Information

The Elecsys Anti-HCV assay shall not be used by blood banks, donor centers, or other institutions which exclusively or predominantly use the test for the safety or screening of blood and blood products.

### Note

Please note that the catalogue number appearing on the package insert retains only the first 8 digits of the licensed 11-digit Catalogue Number: 03290352190 for the Anti-HCV assay. The last 3 digits -190 have been replaced by -119 for logistic purposes.

### Summary

Hepatitis C virus, first identified in 1989, is the most common cause of posttransfusion and community-acquired non-A, non-B hepatitis worldwide. Infection with HCV frequently leads to chronic hepatitis and cirrhosis, and is associated with the development of hepatocellular carcinoma. Common extrahepatic manifestations comprise mixed cryoglobulinemia and other rheumatic diseases.

Hepatitis C virus is an enveloped, positive single-stranded RNA virus which has been classified as an own genus in the family of Flaviviridae. The genome consists of ~9.5 kb encoding for a 3000 amino acid polypeptide of structural and non-structural domains. Like other RNA viruses, the HCV genome exhibits substantial heterogeneity as a result of mutations that occur during viral replication. Worldwide, at least 11 genetically distinct genotypes and multiple subtypes and virus variants have been described. Infection with specific genotypes can affect disease severity and treatment response. Hepatitis C is primarily transmitted through contaminated blood and blood products and to a lower extent by human body secretions.

Anti-HCV antibody tests are used alone or in combination with other tests (e.g. HCV RNA to detect an infection with hepatitis C virus and to identify blood and blood products of individuals infected with HCV.

The Elecsys Anti-HCV assay is a third generation test. The assay uses peptides and recombinant antigens representing core, NS3 and NS4 proteins for the determination of anti-HCV antibodies.

### Test principle

**Sandwich principle.** Total duration of assay: 18 minutes.

- 1st incubation: 40 µL of sample, 60 µL of a reagent containing biotinylated HCV antigens and 60 µL of a reagent containing HCV antigens labeled with a ruthenium complex react to form a sandwich complex.
- 2nd incubation: After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.

### System

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

#### Reagents - working solutions

The reagent rackpack (M, R1, R2, R1a, R2a, R1b, R2b) is labeled as A HCV.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 0.72 mg/mL; preservative.
- R1 Buffer (gray cap), 1 bottle, 7 mL: HEPES buffer, pH 5.0.
- R2 Buffer (black cap), 1 bottle, 7 mL: HEPES buffer, pH 5.0.
- R1a Lyophilized HCV antigens, biotinylated (gray cap), 1 bottle for 1.2 mL solution.
- R2a Lyophilized HCV antigens, ruthenylated (black cap), 1 bottle for 1.2 mL solution.
- R1b Reconstitution medium for bottle R1a (gray cap), 1 bottle, 1.4 mL: Water, preservative.
- R2b Reconstitution medium for bottle R2a (black cap), 1 bottle, 1.4 mL: Water, preservative.

#### Precautions and warnings

For in vitro diagnostic use. Exercise normal precautions required for handling all laboratory reagents. Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request. All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV (A HCV Cal1 only) and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A. The reagent containing anti-HCV (A HCV Cal2) was inactivated using β-propiolactone and UV radiation.

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**cobas®**

**MODULAR ANALYTICS E170**

**cobas e 411**

**cobas e 601**

**cobas e 602**
**Anti-HCV**

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However, as no inactivation or testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.  

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

The Elecsys Anti-HCV assay has a high dilution sensitivity. Avoid any sample cross-contamination during sample pre-analysis.

**Reagent handling**

The reagents R1 and R2 are not ready for use and have to be prepared. See “Preparation of working solutions” section for further instructions. The reagents M, A HCV Cal1 and A HCV Cal2 are ready for use and are supplied in bottles compatible with the system.

**Preparation of working solutions**

The reagents R1 and R2 are not ready for use and have to be prepared by adding the reconstituted antigens.

For the reconstitution of the lyophilized antigens proceed as follows:

1. **Using adapters**
   1a. Connect bottle R1a (lyophilized biotinylated antigens; gray cap) with bottle R1b (reconstitution medium for bottle R1a; gray cap) using one of the adapters. Transfer the volume of reconstitution medium. Avoid foam formation!
   1b. Connect bottle R2a (lyophilized ruthenylated antigens; black cap) with bottle R2b (reconstitution medium for bottle R2a; black cap) using one of the adapters. Transfer the volume of reconstitution medium. Avoid foam formation!

2. Reconstitute the lyophilisates during 30 min ± 5 min by occasionally gently swirling until the lyophilisates are completely dissolved. Avoid foam formation!

3. Remove empty bottles from adapters.

4a. Transfer the volume of the reconstituted Bi-antigen solution R1a (gray cap) into the R1 of the rackpack (gray cap).

4b. Transfer the volume of the reconstituted Ru-antigen solution R2a (black cap) into the R2 of the rackpack (black cap).

5. Produce homogeneous solutions (R1 and R2) by occasionally gently swirling from time to time during a time period of 15 min. Avoid foam formation!

6. Incubate the reconstituted reagent for at least 12 hours at 2-8 °C to finalize the reconstitution process. Overnight storage (e.g., 16 hours at 2-8 °C) is recommended. Reagent kit with R1 and R2 working solution is now ready for use.

6a. Alternatively, the solution prepared under 5. may be used without further incubation. In this case increased control frequency within the first 24 hours of use is recommended. A calibration should be performed after 12-24 hours.

7. Always store the kit containing the working solution R1/R2 at 2-8 °C when not in use. A stability of 14 days can only be guaranteed if R1 and R2 containing the HCV antigens are stored at 2-8 °C, and are not subjected to heat stress.

Note: When transferring the solutions using the adapter, a volume of < 200 μL remains. This remaining volume does not need to be transferred by additional pipetting.

B. Or alternatively by pipetting:

1a. Pipette 1.2 mL of R1b (reconstitution medium; gray cap) into R1a (lyophilized biotinylated antigens; gray cap).

1b. Pipette 1.2 mL of R2b (reconstitution medium; black cap) into R2a (lyophilized ruthenylated antigens; black cap).

2. Reconstitute the lyophilisates during 30 min ± 5 min by occasionally gently swirling until the lyophilisates are completely dissolved. Avoid foam formation!

3a. Pipette 1 mL of this reconstituted Bi-antigen solution R1a (gray cap) into R1 of the rackpack (gray cap).

3b. Pipette 1 mL of this reconstituted Ru-antigen solution R2a (black cap) into R2 of the rackpack (black cap).

4. Produce homogeneous solutions (R1 and R2) by occasionally gently swirling from time to time during a time period of 15 min. Avoid foam formation!

5a. Incubate the reconstituted reagent for at least 12 hours at 2-8 °C to finalize the reconstitution process. Overnight storage (e.g., 16 hours at 2-8 °C) is recommended. Reagent kit with R1 and R2 working solution is now ready for use.

5b. Alternatively, the solution prepared under 4. may be used without further incubation. In this case increased control frequency within the first 24 hours of use is recommended. A calibration should be performed after 12-24 hours.

6. Always store the kit containing the working solution R1/R2 at 2-8 °C when not in use. A stability of 14 days can only be guaranteed if R1/R2 containing the HCV antigens are stored at 2-8 °C, and are not subjected to heat stress.

**Storage and stability**

Store at 2-8 °C.

Return to storage after use. Ensure the reagents are at 20 ± 5 °C prior to use. Do not freeze.

Store the Elecsys reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

<table>
<thead>
<tr>
<th>Stability of the reagent kit and rackpack</th>
<th>reagent kit unopened at 2-8 °C</th>
<th>up to the stated expiration date</th>
</tr>
</thead>
<tbody>
<tr>
<td>reagent kit packed (including reconstituted antigens) at 2-8 °C</td>
<td>2 weeks</td>
<td></td>
</tr>
<tr>
<td>on the analyzers</td>
<td>72 hours if continuously stored on board (20 ± 5 °C) or 2 weeks and up to 40 hours in total on board (20 ± 25 °C) if stored alternately in the refrigerator and on the analyzer</td>
<td></td>
</tr>
</tbody>
</table>
Due to possible evaporation effects, samples, calibrators and controls on the measurement. Centrifuge samples containing precipitates before performing the assay.

The sample types listed were tested with a selection of sample collection tubes from various manufacturers. Only the specimens listed below were tested in a sufficient number and found acceptable.

- PreciControl Anti HCV, for 8 x 1.3 mL each of HCV before 1600 (MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers).
- HCV rackpack is recommended as HCV exists.
- HCV Cal1): 350
- HCV Cal2): 10000
- HCV exists.

The sample types listed were tested with a selection of sample collection tubes from various manufacturers. Only the specimens listed below were tested in a sufficient number and found acceptable.

- PreciControl Anti HCV, for 8 x 1.3 mL each of HCV before 1600 (MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers).
- HCV rackpack is recommended as HCV exists.
- HCV Cal1): 350
- HCV Cal2): 10000
- HCV exists.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/ measured within 2 hours.

Materials provided
See “Reagents – working solutions” section for reagents.
- 2 x 6 bottle labels
- 2 adapters

Materials required (but not provided)
- 03290797190, PreciControl Anti HCV, for 8 x 1.3 mL each of PreciControl Anti HCV 1 and 2
- General laboratory equipment
- Elecsys 2010, MODULAR ANALYTICS E170 or cobas e analyzer

Accessories for Elecsys 2010 and cobas e 411 analyzers:
- 11662988122, PreClean M, 5 x 600 mL detection cleaning solution
- 11930346122, PreClean M, 5 x 600 mL cleaning
- 11662970122, ProCell M, 6 x 380 mL system buffer
- 11706799001, Elecsys 2010 AssayTip, 30 x 120 pipette tips
- 11933159001, Adapter for SysClean
- 11706802001, Elecsys 2010 AssayCup, 60 x 60 reaction vessels
- 11706801001, Elecsys 2010 AssayTip/AssayCup Combimagazine M, 48 magazines x 84 reaction vessels or pipette tips, waste bags
- 12102137001, AssayTip/AssayCup Combimagazine M, 48 magazines x 84 reaction vessels or pipette tips, waste bags
- 0302315001, WasteLiner, waste bags
- 03027651001, SysClean Adapter M

Accessories for all analyzers:
- 11298500316, Elecsys SysClean, 5 x 100 mL system cleaning solution

Specimen collection and preparation
Only the specimens listed below were tested in a sufficient number and found acceptable.

- Serum collected using standard sampling tubes or tubes containing separating gel. Li-, Na heparin, K3 EDTA and sodium citrate plasma.
- Criterion: Correct assignment of negative and positive samples within a recovery of 80 ± 20 % of serum value.
- Stable for 21 days at 2-8 °C, 3 days at 25 °C, 3 months at ±20 °C. Only freeze 6 times.
- The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.
- Centrifuge samples containing precipitates before performing the assay. Ensure the samples, calibrators and controls are at 20 ± 25 °C prior to measurement.
- Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/ measured within 2 hours.

Assay
For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions. Resuspension of the microparticles takes place automatically prior to use.

Read in the test Specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers. MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers: PreClean M solution is necessary. Bring the cooled reagents to approx. 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.
Place the calibrators in the sample zone.
All the information necessary for calibrating the assay is automatically read into the analyzer.
After calibration has been performed, store the calibrators at 2-8 °C or discard (MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers).

Calibration
Calibration frequency:

- Every Elecsys Anti HCV rackpack must be calibrated using A HCV Cal1 and A HCV Cal2. Lot calibrations are not allowed for the Elecsys Anti HCV assay.
- Renewed calibration for each Elecsys Anti HCV rackpack is recommended as follows:
  - after 7 days (when the same reagent kit is alternately used on the analyzer and refrigerated)
  - after 12 (24 hours if the preparation of working solutions is performed according to 6b, (using adapters) or 5b. (by pipetting)
  - as required: e.g. quality control findings outside the defined limits
  - more frequently when this is required by pertinent regulations
- Range for electrochemiluminescence signals (counts) for the calibrators: Negative calibrator (A HCV Cal1): 350 ± 1200 (Elecsys 2010 and cobas e 411 analyzers) or 350 ± 1600 (MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers).
- Positive calibrator (A HCV Cal2): 10000 ± 8000 (Elecsys 2010 and cobas e 411 analyzers) or 10000 ± 6000 (MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers).
- No internationally accepted standard for anti HCV exists.

Quality control
For quality control, use PreciControl Anti HCV.

Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.
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If necessary, repeat the measurement of the samples concerned. Follow the applicable government regulations and local guidelines for quality control.

Note: For technical reasons re-assigned target values valid only for a specific reagent and control lot combination, must be entered manually on all analyzers (except for the cobas e 602 analyzer). Therefore always refer to the value sheet included in the rackpack or PreciControl kit to make sure that the correct target values are used.

When a new reagent or control lot is used, the analyzer will use the original values encoded in the control barcodes.

Calculation
The analyzer automatically calculates the cutoff based on the measurement of A HCV Cal1 and A HCV Cal2.

The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index (signal/sample/cutoff).

Interpretation of the results:
Samples with a cutoff index < 0.9 are non-reactive in the Elecsys Anti HCV assay.
Samples having a cutoff index between ≥ 0.9 and < 1.0 are considered borderline in the Elecsys Anti HCV assay.
Samples with a cutoff index ≥ 1.0 are reactive in the Elecsys Anti HCV assay. All initially reactive or borderline samples should be redetermined in duplicate using the Elecsys Anti HCV assay.

If no reactivity is found in both cases, the sample is negative for anti-HCV. If the result from either of the two measurements is reactive or borderline then the sample is repeatedly reactive. Repeatedly reactive samples must be investigated by supplemental methods (e.g. immunoblot or detection of HCV RNA). If one or both measurements remain borderline the analysis of a follow-up sample is recommended.

Limitations - interference
The assay is unaffected by icterus (bilirubin < 655µmol/L or < 50mg/dL), hemolysis (Hb < 1.09mmol/L or < 1.75g/dL), lipemia (Intralipid < 2100mg/dL) and biotin (50ng/mL or < 205nmol/L).

Criterion: Recovery of positive samples within ± 20% of initial value, cutoff index between
samples < 0.5.

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5mg/day) until at least 8 hours following the last biotin administration.

No interference was observed from rheumatoid factors up to a concentration of 1000 IU/mL.

No false negative result due to high bone hook effect was found with the Elecsys Anti HCV assay.

In vitro tests were performed on 18 commonly used pharmaceuticals and 2 drugs used in HCV therapy. No interference with the assay was found. In rare cases, interference due to extremely high titers of antibodies to streptavidin and ruthenium can occur.

For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings.

Due to a long time period from infection to seroconversion, negative anti HCV test results may occur during early infection. If acute hepatitis C infection is suspected, measuring of HCV RNA by reverse transcriptase polymerase chain reaction (RT PCR e.g. by COBAS AMPLICOR) may give evidence of HCV infection.

The detection of anti HCV antibodies indicates a present or past infection with hepatitis C virus, but does not differentiate between acute, chronic or resolved infection. It is recognized within the scientific community that presently available methods for anti HCV detection are not sensitive enough to detect all potentially infectious units of blood or possible cases of HCV infection.

The antibody concentration may be beneath the detection limit of this assay or the patient’s antibodies do not react with the antigens used in this test. In addition, non-specific results cannot be ruled out with the Elecsys Anti HCV assay.

Specific performance data
Representative performance data on the analyzers are given below.

<table>
<thead>
<tr>
<th>Elecsys 2010 and cobas e411 analyzers</th>
<th>Repeatability&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Intermediate precision&lt;sup&gt;d&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Mean COI&lt;sup&gt;e&lt;/sup&gt;</td>
<td>SD COI</td>
</tr>
<tr>
<td>HS&lt;sup&gt;f&lt;/sup&gt;, negative</td>
<td>0.11</td>
<td>0.01</td>
</tr>
<tr>
<td>HS, weakly positive</td>
<td>4.15</td>
<td>0.14</td>
</tr>
<tr>
<td>HS, positive</td>
<td>34.7</td>
<td>0.38</td>
</tr>
<tr>
<td>PreciControl A-HCV1</td>
<td>0.14</td>
<td>0.01</td>
</tr>
<tr>
<td>PreciControl A-HCV2</td>
<td>8.67</td>
<td>0.11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MODULAR ANALYTICS E170, cobas e601 and cobas e602 analyzers</th>
<th>Repeatability&lt;sup&gt;g&lt;/sup&gt;</th>
<th>Intermediate precision&lt;sup&gt;h&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample</td>
<td>Mean COI</td>
<td>SD COI</td>
</tr>
<tr>
<td>HS, negative</td>
<td>0.084</td>
<td>0.020</td>
</tr>
<tr>
<td>HS, weakly positive</td>
<td>3.14</td>
<td>0.143</td>
</tr>
<tr>
<td>HS, positive</td>
<td>72.8</td>
<td>2.23</td>
</tr>
<tr>
<td>PreciControl A-HCV1</td>
<td>0.052</td>
<td>0.007</td>
</tr>
<tr>
<td>PreciControl A-HCV2</td>
<td>11.7</td>
<td>0.241</td>
</tr>
</tbody>
</table>

Analytical specificity
774 samples containing potentially interfering substances were tested with the Elecsys Anti HCV assay comprising specimens:

- containing antibodies against HBV, HAV, HEV, EBV, CMV, HSV, HIV, Rubella, Toxoplasma gondii, Treponema pallidum
- containing autoantibodies and elevated titers of rheumatoid factor, IgG, IgM or IgA antibodies
- positive for HBsAg and E. coli
- after vaccination against HBV and influenza
- non-viral liver diseases
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<table>
<thead>
<tr>
<th>Specimens containing potentially interfering substances</th>
<th>N</th>
<th>Elecsys Anti-HCV reactive</th>
<th>Positive by immunoblot or indeterminate</th>
<th>Negative by immunoblot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimens containing potentially interfering substances</td>
<td>774</td>
<td>29</td>
<td>21 positive 3 indeterminate</td>
<td>5</td>
</tr>
</tbody>
</table>

Patient with autoantibodies: 1 out of 164 samples, HBV infected: 2 out of 87 samples, EBV infected: 1 out of 61 samples, non viral liver diseases: 1 out of 24 samples

Clinical sensitivity
Of 1057 samples from HCV infected patients with different stages of disease and infected with different HCV genotypes (type 1, 2, 3, 4, 5, and 6), all samples were found to be reactive with the Elecsys Anti-HCV assay.

Seroconversion sensitivity
Seroconversion sensitivity of the Elecsys Anti-HCV assay was found 99.71 % (RR). The 95 % lower confidence limit was 99.58 %.

Clinical specificity
In the study above the diagnostic sensitivity was found 100 %. The 95 % lower confidence limit was 99.72 %.

Seroconversion sensitivity
Seroconversion sensitivity of the Elecsys Anti-HCV assay has been shown by testing 50 commercial seroconversion panels in comparison to other registered anti-HCV immunoassays.

Clinical specificity
In a group of randomly selected European blood donors the specificity of the Elecsys Anti-HCV assay was found 99.71 % (RR). The 95 % lower confidence limit was 99.58 %.

The diagnostic specificity of the Elecsys Anti-HCV assay in a group of hospitalized patients, dialysis patients and pregnant women was found 99.17 %. The 95 % lower confidence limit was 98.76 %.

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV infected persons with different stages of disease</td>
<td>813</td>
<td>813</td>
</tr>
<tr>
<td>HCV genotypes (type 1, 2, 3, 4, 5, 6)</td>
<td>244</td>
<td>244</td>
</tr>
</tbody>
</table>

In the study above the diagnostic specificity was found 100 %. The 95 % lower confidence limit was 99.72 %.

References

For further information, please refer to the appropriate operator’s manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country). A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols
Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-11 standard.

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>CONTENT</th>
<th>SYSTEM</th>
<th>REAGENT</th>
<th>CALIBRATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analyzer/Instrument</td>
<td>Content of kit</td>
<td>Analyzers/Instruments on which reagents can be used</td>
<td>Reagent</td>
<td>Calibrator</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Volume after reconstitution or mixing</td>
</tr>
</tbody>
</table>

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