**Procleix Ultrio Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents**

*For In Vitro Diagnostic Use*

**INTENDED USE**
The Procleix Ultrio Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are to be used with the Procleix Ultrio Plus Assay. Procleix Ultrio Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are provided for use in discriminating between HIV-1, HCV, and HBV in human plasma or serum found to be reactive with the Procleix Ultrio Plus Assay.

**SUMMARY AND EXPLANATION OF THE TEST**
The Procleix Ultrio Plus Assay is a qualitative in vitro nucleic acid amplification test for the detection of human immunodeficiency virus type 1 (HIV-1) RNA, hepatitis C virus (HCV) RNA, and/or hepatitis B virus (HBV) DNA in plasma and serum specimens from human donors. For specimens that are reactive in the Procleix Ultrio Plus Assay, the Procleix Ultrio Plus Discriminatory Probe Reagents allow discrimination between HIV-1, HCV, and HBV reactivity. The Procleix Ultrio Plus Assay incorporates an Internal Control for monitoring assay performance in each individual specimen.

**PRINCIPLES OF THE PROCEDURE**
The Procleix Ultrio Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are used with the Procleix Ultrio Plus Assay. Principles of the procedure for their use are given in the Procleix Ultrio Plus Assay package insert.

**REAGENTS**
Each of the Procleix Ultrio Plus Discriminatory Probe Reagents for the Procleix Ultrio Plus Assay is provided separately:

- HIV-1 Discriminatory Probe Reagent - 200 Tests, P/N 302571
- HCV Discriminatory Probe Reagent - 200 Tests, P/N 302577
- HBV Discriminatory Probe Reagent - 200 Tests, P/N 302576

Store unopened reagent at -15° to -35°C.

**CONTENTS**

<table>
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<tr>
<th>P/N</th>
<th>Reagent Name</th>
<th>Number of vials/Volume per vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>302571</td>
<td>HIV-1 Discriminatory Probe Reagent</td>
<td>2 x 14 mL</td>
</tr>
<tr>
<td></td>
<td><em>Chromiluminescent oligonucleotide probe in succinate buffered solution containing detergent.</em></td>
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<tr>
<td>302577</td>
<td>HCV Discriminatory Probe Reagent</td>
<td>2 x 14 mL</td>
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<tr>
<td></td>
<td><em>Chromiluminescent oligonucleotide probe in succinate buffered solution containing detergent.</em></td>
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<tr>
<td>302576</td>
<td>HBV Discriminatory Probe Reagent</td>
<td>2 x 14 mL</td>
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<tr>
<td></td>
<td><em>Chromiluminescent oligonucleotide probe in succinate buffered solution containing detergent.</em></td>
<td></td>
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</tbody>
</table>

**PRECAUTIONS**

- **A. For In Vitro Diagnostic Use.**
- **B.** Use routine laboratory precautions. Do not pipette by mouth; do not eat, drink, or smoke in the laboratory work area. Wash hands thoroughly after handling Procleix Ultrio Plus HIV-1, HCV, or HBV Discriminatory Probe Reagents.
- **C.** Avoid microbial and ribonuclease contamination of the Procleix Ultrio Plus Discriminatory Probe Reagents.

*Developed by Hologic, Inc. in collaboration with Grifols Diagnostic Solutions Inc.; Manufactured by Hologic, Inc.*
STORAGE INSTRUCTIONS

A. The Procleix Ultro Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are light-sensitive. Protect these reagents from light during storage and preparation for use.

B. The Procleix Ultro Plus Discriminatory Probe Reagents are stable when stored unopened at -15°C to -35°C until the expiration date. Do not use after the expiration date.

C. If precipitate forms during storage, warm to 15°C to 30°C and mix thoroughly prior to use.

REAGENT PREPARATION

A. Thaw Procleix Ultro Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents at room temperature (15°C to 30°C) or at 2°C to 8°C and mix thoroughly by inversion or by vortexing. Record date of thaw (THAW DATE) in the space provided on the label.

B. If using a water bath, DO NOT heat the HIV-1 Discriminatory Probe Reagent, the HCV Discriminatory Probe Reagent, or the HBV Discriminatory Probe Reagent above 30°C. If using the Reagent Preparation Incubator (RPI), DO NOT heat the HIV-1 Discriminatory Probe Reagent, HCV Discriminatory Probe Reagent, or the HBV Discriminatory Probe Reagent above 35°C. Refer to the appropriate Procleix System Quick Reference Guide (QRG).

C. After thawing, the Procleix Ultro Plus Discriminatory Probe Reagents are stable when stored at 2°C to 8°C for 30 days. Within the 30 days, these reagents may be kept at room temperature up to a total of 80 hours. Do not refreeze these reagents after the initial thaw.

D. Precipitate will form in the Procleix Ultro Plus Discriminatory Probe Reagents when stored at 2°C to 8°C. Procleix Ultro Plus Discriminatory Probe Reagents may be warmed in a water bath to facilitate dissolution of precipitate, but temperature in the water bath should not exceed 30°C. If thawing is conducted on the lab bench, Procleix Ultro Plus Discriminatory Probe Reagents may take up to 4 hours with periodic mixing to allow complete dissolution of precipitate. Alternatively, use the RPI to thaw the Procleix Ultro Plus Discriminatory Probe Reagents at an average temperature of 32 ± 2°C not to exceed 35°C. Refer to the appropriate Procleix System QRG. Ensure that precipitates in the Procleix Ultro Plus Discriminatory Probe Reagents are dissolved. If precipitate is still present after thawing, the probe reagents can be incubated at room temperature in a water bath or the RPI to facilitate complete dissolution of precipitate, as long as the total time at room temperature does not exceed 80 hours. Do not use if precipitate or cloudiness is present.

PROCEDURE

Procleix Ultro Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are master lotted with the Procleix Ultro Plus Assay reagents. The operator must check to ensure that the Procleix Ultro Plus Discriminatory Probe Reagents are used with the corresponding master lot of kit reagents as indicated on the Procleix Ultro Plus Assay master lot sheet in use.

MATERIALS PROVIDED

Each Procleix Ultro Plus Discriminatory Probe Reagent for the Procleix Ultro Plus Assay is provided separately:

- HIV-1 Discriminatory Probe Reagent: P/N 302571
- HCV Discriminatory Probe Reagent: P/N 302577
- HBV Discriminatory Probe Reagent: P/N 302576

MATERIALS REQUIRED BUT NOT PROVIDED


INSTRUCTIONS FOR USE

Procleix Ultro Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are used in the Procleix Ultro Plus Assay as described in the Procleix Ultro Plus Assay package insert.

LIMITATIONS OF THE PROCEDURE

Assays must be performed, and results interpreted, according to the procedures provided in the Procleix Ultro Plus Assay package insert.

Deviations from these procedures, adverse shipping and/or storage conditions, or use of outdated Procleix Ultro Plus HIV-1, HCV, or HBV Discriminatory Probe Reagents may produce unreliable results.

EXPECTED RESULTS

Please reference the QUALITY CONTROL PROCEDURES and INTERPRETATION OF RESULTS sections of the Procleix Ultro Plus Assay package insert for expected results.
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