

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

For *In Vitro* Diagnostic Use

IVD

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


P/N	Reagent Name	Number of vials/ Volume per vial
302571	HIV-1 Discriminatory Probe Reagent <i>Chemiluminescent oligonucleotide probe in succinate buffered solution containing detergent.</i>	2 x 14 mL D1
302577	HCV Discriminatory Probe Reagent <i>Chemiluminescent oligonucleotide probe in succinate buffered solution containing detergent.</i>	2 x 14 mL D2
302576	HBV Discriminatory Probe Reagent <i>Chemiluminescent oligonucleotide probe in succinate buffered solution containing detergent.</i>	2 x 14 mL D3

PRECAUTIONS

- For *In Vitro* Diagnostic Use.**
- 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.
- 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 Ultrio 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 Ultrio Plus Discriminatory Probe Reagents are stable when stored unopened at -15° to -35°C until the expiration date. Do not use after the expiration date.
- C. If precipitate forms during storage, warm to 15° to 30°C and mix thoroughly prior to use.

REAGENT PREPARATION

- A. Thaw Procleix Ultrio Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents at room temperature (15° to 30°C) or at 2° 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 Ultrio Plus Discriminatory Probe Reagents are stable when stored at 2° 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 Ultrio Plus Discriminatory Probe Reagents when stored at 2° to 8°C. Procleix Ultrio 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 Ultrio 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 Ultrio 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 Ultrio 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 Ultrio Plus HIV-1, HCV, and HBV Discriminatory Probe Reagents are master lotted with the Procleix Ultrio Plus Assay reagents. The operator must check to ensure that the Procleix Ultrio Plus Discriminatory Probe Reagents are used with the corresponding master lot of kit reagents as indicated on the Procleix Ultrio Plus Assay master lot sheet in use.

MATERIALS PROVIDED

Each Procleix Ultrio Plus Discriminatory Probe Reagent for the Procleix Ultrio 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

Procleix Ultrio Plus Assay. Refer to the Procleix Ultrio Plus Assay package insert.

INSTRUCTIONS FOR USE

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

LIMITATIONS OF THE PROCEDURE

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

Deviations from these procedures, adverse shipping and/or storage conditions, or use of outdated Procleix Ultrio 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 Ultrio Plus Assay package insert for expected results.



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