March 3, 2020

**Grifols Procleix Ultrio Elite Assay Implementation on the Panther Testing Platform**

**Overview:**

Beginning on June 1, 2020, all 5 CTS laboratories will transition (over a 30-day period) from the Procleix Ultrio Plus assay to the Procleix Ultrio Elite assay using the Grifols fully automated Panther System. Implementing the Ultrio Elite assay will allow CTS to exclusively use the newer Panther instruments for all NAT-based testing, completing our move away from the older Grifols Tigris instruments. This newer Panther NAT testing platform transition will increase testing efficiency and also includes the enhanced claim for identification of HIV-2 virus. This implementation should not interrupt your normal testing schedule.

While the sample requirements for the Procleix Ultrio Elite assay remain the same as Ultrio Plus, the package insert has been updated to reflect the assay performance on the Panther System. The assay license number has not changed. The new package insert, updated interpretation information sheets, assay history list, and platform history list will be available on the CTS website on June 1st.

The Procleix Ultrio Elite assay is a qualitative *in vitro* nucleic acid amplification test to screen for, hepatitis C virus (HCV) RNA, hepatitis B virus (HBV) DNA, and human immunodeficiency virus types 1 (HIV-1) and 2 (HIV-2) RNA in plasma and serum specimens from individual human donors, including donors of whole blood, blood components, source plasma, and from other living donors.

**Impact to Clients:**

- The new Ultrio Elite assay package insert, assay history list, and platform history list will be available on the CTS website on June 1st.
- No change to sample requirements.
- No change to result format for Ultrio Elite assay.
- No expected delay in testing during the implementation.

**Client Action Required:**

- Notify appropriate staff of updated documents on the website.

**Questions and Additional Information:**
Please email your questions or requests for additional information to Claudia Barnett (cbarnett@mycts.org) or Larry Morgan (lmorgan@mycts.org).