

3.0 510(k) Summary of Safety and Effectiveness

The 510(k) Summary of Safety and Effectiveness has been updated to include the following features of the PROCLEIX[®] NAT TRACKER[®] v3.0 software and is provided in **Appendix 3**.

Additional Functionality

Procleix[®] TIGRIS[®] System for use with the Procleix[®] Ultrio[®] and Procleix[®] WNV Assays

The software has been modified to accept and retain data generated on the Procleix[®] TIGRIS[®] System for use with the Procleix[®] Ultrio[®] and Procleix[®] WNV Assays.

Interim Pool Conclusions

The software has been modified to add the ability to optionally assign and report interim pool reactive and pool nonreactive conclusions for associated samples in order to provide notification of testing status.

Multiple Pathways

The software has been modified to add an option to define up to 15 pathways for results import.

Option External Quality Control Management

The software has been modified to add an option for users to define whether external quality controls are mandatory as part of the release of results from NAT TRACKER. The user defined option allows for entry of acceptable sample to cut off ranges.

Laboratory Information System Output Files

The software has been modified to add the option to report results in laboratory information system output files based on client identification number. An optional new "Secondary Format" was added to the existing laboratory information system output files. An option to add a Cyclic Redundancy Check (CRC) to "Standard Formats" output files was also incorporated in this version.

Gravimetric Acceptance of Predefined Ranges

The software has been modified to add predefined gravimetric ranges for pools sizes. The option for customer defined gravimetric ranges was removed from the software.

Software Anomaly Corrections

Two software anomalies discovered in Proclex[®] NAT Tracker[™] Version 2.1 software were corrected in the PROCLEIX[®] NAT TRACKER[®] version 3.0 software.

- a) to correct the summary of results print preview and report anomaly (SBR-0030)

The "Unit IDs imported" field on the "Results of pool import" screen, "Preview Results of Pool File Import Operation" screen and Results of Pool File Import Operation" contained a 3 character limit and could only display a maximum value of 999 even when a greater number of Unit IDs were imported by a user during a session. The "Unit IDs imported" field on these screens and the associated report shall be expanded to display up to 4 characters in PROCLEIX[®] NAT TRACKER[®] version 3.0.

- b) to correct the table display anomaly (SBR-044)

The plotted values in certain reports (the run performance indicator screens) did not display upon initial launch. The user was instructed in the operator's manual to press the tab button to view the plotted value selections. The plotted values display upon initial launch of the screen in PROCLEIX[®] NAT TRACKER[®] version 3.0.