

Release Notes

Agilent CytoDx v2.1.0.9

Product Number

K1203AA – "CytoDx Client 1 year named" license (including Feature Extraction for CytoDx). This license supports installation of one client and server (to host the CytoDx database) on one machine. For additional client-only installations, which connect to the same database on the central server, additional copies of this license are needed.

Overview

The Agilent CytoDx software is used to analyze microarray images obtained with the Agilent GenetiSure Dx Postnatal Assay. This assay is a qualitative assay intended for postnatal detection of copy number variations (CNV) and copy-neutral losses of heterozygosity (cnLOH) in genomic DNA obtained from blood samples. CytoDx performs feature extraction on the microarray image, identifies CNV and cnLOH aberrations using a predefined analysis method, and generates reports on the sample results. There are four different user roles in CytoDx: System Admin, Technician, Cytogeneticist, and Lab Director. System Admins are responsible for installing the software, administering user functions, configuring the software, and viewing activity logs and audit trails. In a typical CytoDx workflow, the Technician is responsible for running the analysis on the sample files. The Cytogeneticist or Lab Director then reviews, interprets, classifies, and, if necessary, edits the aberrations assigned to the sample, all of which is recorded in the audit trail. The Lab Director is ultimately responsible for reviewing sample results and signing off on those results, which prompts generation of the final report.

Key features of CytoDx

- Streamlined workflow for data analysis with full automation of data upload and analysis.
- Validated algorithms for analysis of the Agilent GenetiSure Dx Postnatal CGH+SNP Microarray data, which identify both copy number variations (CNV) and copy-neutral losses of heterozygosity (cnLOH) with high confidence and accuracy, all in one array.
- Superior graphical displays to visualize and triage the results in an intuitive way.
- Array-level QC metrics that are grouped into "Actionable" and "Informational" categories, giving users confidence in their assay results.
- Pre-loaded tracks and links to external databases for data interpretation evidence support.
- Fully customizable Cyto report, which provides information on the analysis results in tabular and graphical formats according to a specified report template.
- Complete audit trail recording for maximum traceability.

New key features of CytoDx v2.1

- Option to enable the plotting of Aberration Bar Legends in the Genomic Viewer and PDF Cyto reports, which better show the locations of aberrations when CGH Probes scatter plots are included in the display
- Ability to use mouse scrolling to zoom-in/out of the Chromosome View and Cytoband image in Triage View
- Secured communication between the LDAP server and CytoDx client machine during user authentication
- Updated software licensing terms to associate each software license with a specific software version

New key features of CytoDx v2.0

- Performance enhancement to support large sample records in the database
- New layouts for the Triage View data that set the orientation and arrangement of the views while still allowing you to customize and adjust the display
- New Triage View toggle buttons and menus that simplify customization of the display, including undocking views into separate windows and switching between overlaid and stacked data views for triage of multiple sample
- Graphic visualization of QC Metrics for easier comparison of metrics over multiple samples
- New Dynamic Aberration track to compare sample intervals against reviewed records
- Option to allow suppressed calls to be included in dynamic tracks
- Option to export Sample Review table data to file on disk
- Improvements to the Record Search feature that support searching records by attributes, metric values, and date
- Separate program tab containing all Auto-Processing tools on a single screen
- Updated annotations of external source tracks

Default and preloaded content

The hg19 version of the design file for the Agilent GenetiSure Dx Postnatal CGH+SNP Microarray (044577) design.

CytoDx installer comes with the following external tracks:

- 1. Gene_hg19_Feb2022
- 2. CNV_DGV_Sep2020
- 3. Multi Transcripts for Genes Feb2022
- 4. OMIM_Jan2023
- 5. NCBI_RefSeq_Curated_Jan2023

Agilent Feature Extraction for CytoDx

Agilent Feature Extraction (FE) for CytoDx is an important component within CytoDx, which performs TIFF image processing, background subtraction, and normalization of microarray data. Running image extraction is an integral part of the CytoDx analysis workflow. The FE for CytoDx software module runs in the background during the workflow job in order to feature extract the microarray image; users do not need to separately launch FE for CytoDx in order to perform feature extraction. However, if desired, users can open the FE for CytoDx module in order to view TIFF images for visualization and troubleshooting purposes.

System Requirements for Agilent CytoDx computers

Agilent CytoDx consists of two parts: a PostgreSQL database server and the client software. Once you have installed the database server and client software on one computer, you can install additional copies of the client software on client computers that have network access to the database computer.

Recommended Requirements for Windows*

- 1. Requirements for computers running CytoDx Server:
 - a. Operating system: 64-bit Windows 10 Enterprise or Professional, or Windows Server 2016
 - b. CPU: Intel Core i7 or better
 - c. RAM: 8 GB or better
 - d. Disk: 2 TB**
 - e. Display 1280 x 768 or better
 - f. Any program for opening PDF files (for example, Adobe Reader)
- 2. Requirements for computers running CytoDx Client:
 - a. Operating system: 64-bit Windows 10 Enterprise or Professional, or Windows Server 2016
 - b. CPU: Intel Core i7 or better
 - c. RAM: 8 GB or better
 - d. Disk 500 GB.
 - e. Display 1280 x 768 or better
 - f. Any program for opening PDF files (for example, Adobe Reader)

* CytoDx is not supported on Macintosh OS.

** The requirement for 2 TB of disk space is based on the expectation that the server PC will need enough space to store 1000+ sample tiff image files.

Issues fixed in v2.1

- JIRA- CYTODX-300 In PDF report, the image of the CGH&SNP plots do not align with the cytoband image.
- JIRA- CYTODX-301 In PDF report, the cytoband image in the Chromosome View is sometimes cut off at the bottom.
- JIRA- CYTODX-302 In PDF report, the cytoband labels are not properly positioned.
- JIRA- CYTODX-303 In PDF report, the mean log ratio plots does not accommodate aberrations with a mean log ratio value higher than the scale range.

- JIRA- CYTODX-304 Samples may have a gender normal ISCN string even if aberrations were reported on ChrX and ChrY.
- JIRA- CYTODX-305 When no intervals are found in a female sample, the reported ISCN string is missing a closing bracket.
- JIRA- CYTODX-307 In Triage View, genes names in the Gene View are cut off when scale is set to >4.
- JIRA- CYTODX-309 In the QC Metrics dialog box, the color applied to a QC metric in the table may change if the table columns are rearranged.
- JIRA- CYTODX-312 In Triage View, when opening additional samples using the 'Add Record' command, the order in which the samples are opened can differ from the order in which the samples were selected.
- JIRA- CYTODX-313 In Triage View, when multiple samples are open and a sample is closed, the data for the closed sample may still be displayed in the Chromosome and Gene View.
- JIRA- CYTODX-317 On the Sample Review screen, searching for a record based on a QC metric condition set to a value of "NA" does not yield the correct set of results.
- JIRA- CYTODX-321 In Triage View, zooming in/out in the Chromosome View using mouse scrolling causes the aberration intervals count in the corner of the view to change.
- JIRA- CYTODX-323 In the Tracks View of Triage View, when using the 'View in external databases' command for an aberration in a dynamic track, the software searches using the sample name as gene name instead of searching by genomic coordinates.
- JIRA- CYTODX-325 In Triage View, when the View Settings dialog box is used to change the gene name font size, the change does not take effect.
- JIRA- CYTODX-351 Updated commons-text.jar to v1.10 to avoid reported vulnerability (CVE-2022-42889).

Known issues for CytoDx that may impact end users

- TT #294611 Text in the header and footer of the Cyto report PDF is cut off when values to be reported in these sections have 500 or more characters.
- JIRA-CYTODX-103 In Auto-Processing logs, the counts for Images Processed and Samples Processed change when automated workflows are deleted.
- JIRA- CYTODX-262 SNP Pane image in the PDF report does not display the 'Clonal Fraction' metric value.
- JIRA- CYTODX-391 In PDF report images, the scale numbers for some charts are not visible when log scale is set to >2.
- JIRA- CYTODX-397 When an LOH call is manually added to a sample, the software does not calculate an LOH score for the call and erroneously reports the mean log ratio value as the LOH score.
- JIRA- CYTODX-553 The user settings file for CytoDx 1.2 is erroneously erased if CytoDx 2.0 (installed on the same machine) is manually uninstalled and rather than uninstalled with the auto-uninstaller that launches during upgrade from v2.0 to v2.1.

Installer Instructions

Note: To ensure the SAF file names and log files work properly with Japanese characters, Agilent recommends installing CytoDx on a PC with Japanese locale operating system.

New Installation

Refer to the Installation and Set Up Guide available at <u>https://genetisuredx.agilent.com/manuals/cytodx-installation-set-up-guide/</u>

Agilent CytoDx is For In Vitro Diagnostic Use PR7000-3544