

## Release Notes

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### Agilent CytoDx v2.2.0.4

#### 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 v2.2

- New IVDR compliant labelling added to the application.
- Latest versions of CytoDx platform software applications, including Java, Spring, PostgreSQL database, and other 3rd party libraries.
- 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\_Jul2024
5. NCBI\_RefSeq\_Curated\_Jul2024

## 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 11 Enterprise or Professional, Windows 10 Enterprise or Professional, or Windows Server 2022
  - 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 11 Enterprise or Professional, Windows 10 Enterprise or Professional, or Windows Server 2022
- 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 v2.2

- JIRA-CYTODX-615 - At times, user authentication process is slower than expected.
- JIRA-CYTODX-614 - In rare cases, the SNP Genome View image in the Cyto report is not rendered properly.
- JIRA-CYTODX-606 - Link to UCSC genome browser does not always work.
- JIRA-CYTODX-602 - On the Configure Settings > Reports screen, the Apply button on the Other Report Settings tab may remain enabled after changes applied.
- JIRA-CYTODX-601 - On the Sample Review screen, the values in the DLRSD column do not always refresh after a workflow completes.

## 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 the number of characters in these sections exceeds 500.
- 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 instead reports the mean log ratio value as the LOH score.
- JIRA-CYTODX-699 - In PDF reports, when an aberration interval's P-value is set to lowest positive non-zero value (4.9406564584e-324), the value gets rounded to 5.0e-324.
- JIRA- CYTODX-209 - Launching the application takes longer than usual when the application is set to open to the Sample Review screen and number of samples in the database is 125,000 or more.
- JIRA-CYTODX-701 & TT #294408 - Auto-Processing logs may display a question mark in place of Japanese characters in the sample name.
- JIRA- CYTODX-700 - In PDF reports, Gene View images sometimes overlap the user-provided image in the header or footer when that dimensions of that image are too large.

## 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 <https://genetisuredx.agilent.com/manuals/cytodx-installation-set-up-guide/>

*Agilent CytoDx is For In Vitro Diagnostic Use*

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