Agendia Data Analysis Pipeline Tool (ADAPT-CE)

User Guide

For use only in combination with the MammaPrint® BluePrint® Breast Cancer Recurrence and Molecular Subtyping Kit

IVD

For In Vitro Diagnostic Use

AGENDIA®

MAMMAPRINT+BLUEPRINT

EM-002-v4 (2023 December)

Contents

Introduction

This User Guide covers important information on how to use the Agendia Data Analysis Pipeline Tool (ADAPT-CE), which is a high-performance and security-compliant cloud-based genomics analysis platform. ADAPT-CE is intended to be used in combination with the MammaPrint® BluePrint® Breast Cancer Recurrence and Molecular Subtyping Kit (MammaPrint BluePrint Kit). ADAPT-CE delivers integrated analysis and results reporting of samples processed with the MammaPrint BluePrint Kit.

This User Guide will provide step-by-step instructions to create an account, install a secure file connector, upload, and analyze de-identified patient data in a secure environment, and retrieve test results.

Prior to starting, review all instructions in this User Guide. If you still have questions after reading this User Guide, please contact NGS.support@agendia.com for assistance.

System Requirements

ADAPT-CE REQUIREMENTS

ADAPT-CE is a secure cloud-based system which can be accessed through the browsers listed below.

Browser	Supported Version	Operating System
Google Chrome	Most recent stable version	Windows, Mac, and Linux
Mozilla Firefox	Most recent stable version	Windows, Mac, and Linux

For proper functioning of ADAPT-CE, ensure that cookies are enabled in the browser.

AGENDIA SERVICE CONNECTOR REQUIREMENTS

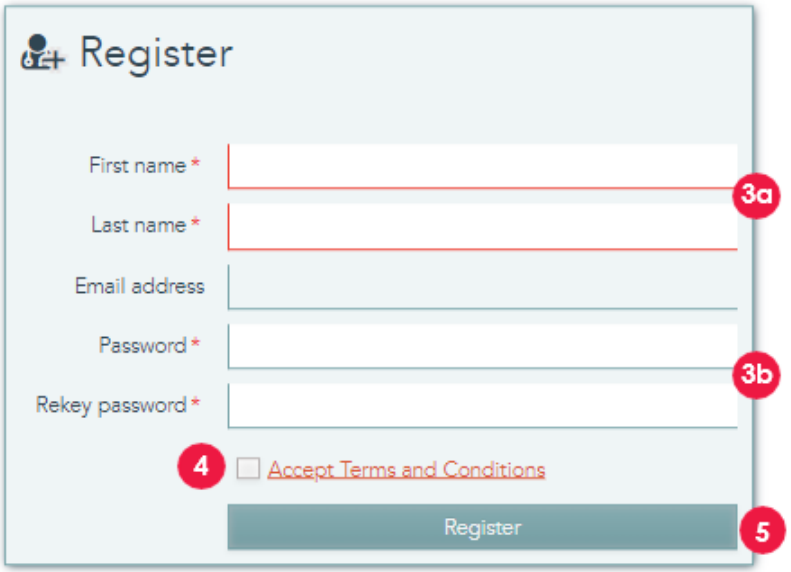
The Agendia Service Connector is a secure file transfer protocol connector that will need to be installed to upload data to ADAPT-CE.

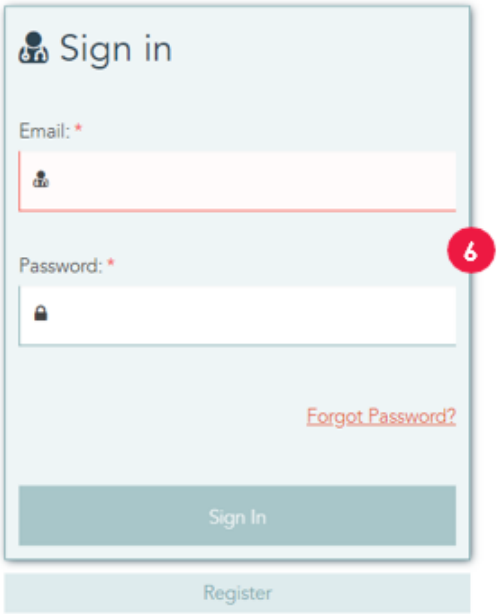
The Agendia Service Connector can be installed in Windows, Mac and Linux environments.

For proper functioning of the connector,

- Ensure that your Internet connection is 1.5 Mbps or faster.
- Ensure the outbound ports TCP443 (SSL) and TCP22 (SSH) are open in firewalls that may be present.

⚠ **CAUTION:** Users may need administrative privileges on their computers to install the Agendia Service Connector and/or to configure firewalls. Consult with your IT Department for assistance.

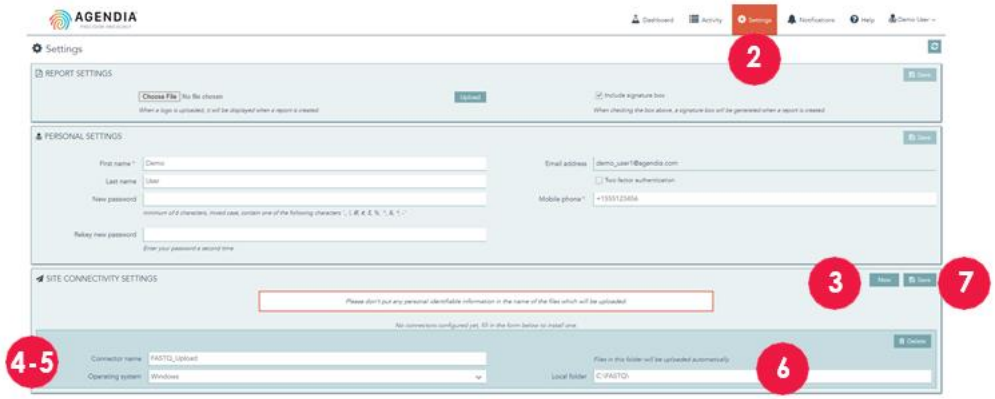


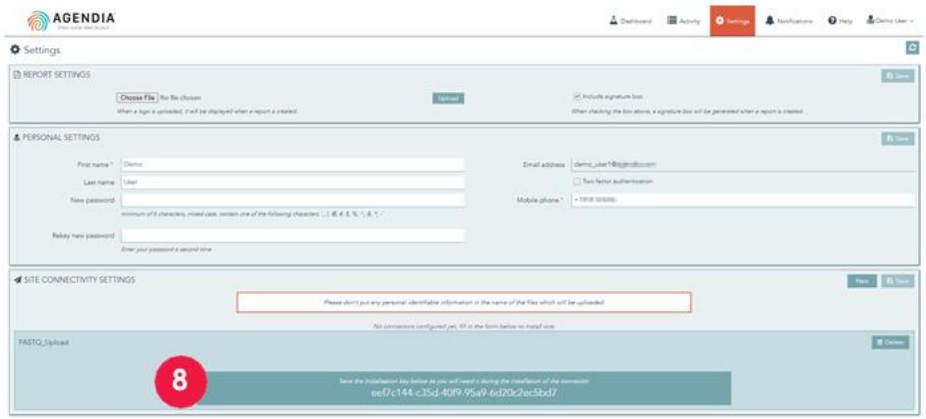


Initial Setup

CREATING AN ADAPT-CE ACCOUNT

1. An automated registration email is sent from Illumina ICA which provides a link to the ADAPT-CE registration portal.
2. Open the link in the email to go to the ADAPT-CE registration portal.
3. Enter the requested information,
   a. First Name & Last Name for your account
   b. To adhere to security requirements, the chosen password must include at least one of the following characters: ! . @ # $ % ^ & *-
4. Review Terms and Conditions and click the check box to Accept.
5. Once you click on "Register", ADAPT-CE will have registered your account details.
6. The page will now refresh with the login screen. Enter your credentials to access to your newly registered account.





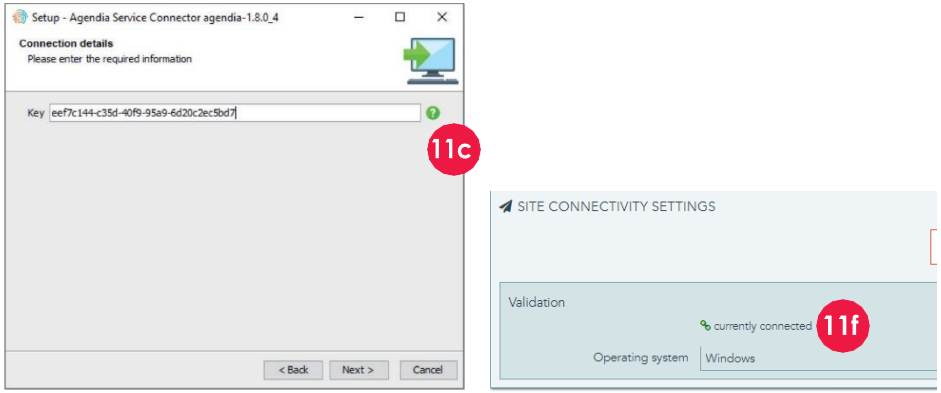
INSTALLING THE AGENDIA SERVICE CONNECTOR

To upload data to ADAPT-CE, you will need to download and install the Agendia Service Connector to ensure a secure and robust file transfer protocol.

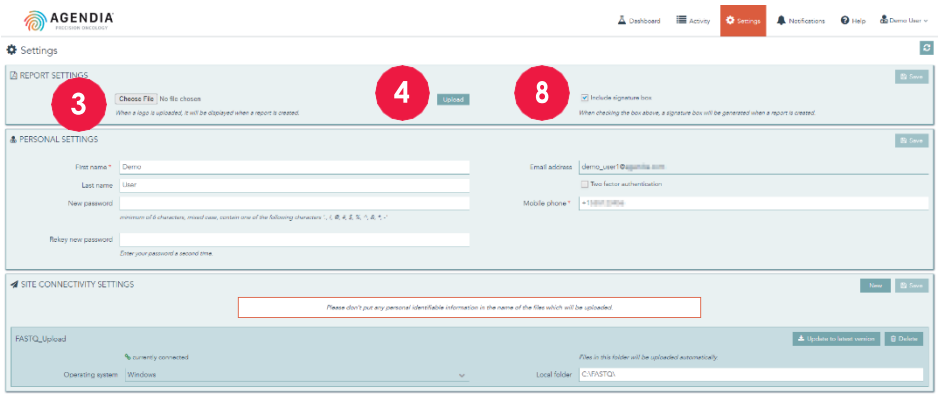
⚠ **CAUTION:** Please consult with your IT Department before installing any software in your business environment.

In addition, ADAPT-CE connector requires the installation and operation of the program to be on a local drive.

1. Log into your ADAPT-CE account at https://ica.illumina.com/ADAPT-CE
   a. When logging in using some browsers, you may need to click "Sign In" twice.
2. In the ADAPT-CE top menu bar, click on "Settings".
3. In the section titled "Site Connectivity Settings", click "New".
4. Enter a unique name for your connector. e.g., "[Site Name] ADAPT-CE Connector".
5. Select your Operating System from the drop-down list (Windows, Mac or Linux).
   a. If you do not know your computer's Operating System, consult with your IT department for assistance.
6. For the "Local folder", provide the Local directory path for the folder containing the relevant FASTQ files that need to be uploaded to ADAPT-CE for analysis.
   a. Example: "C:\ADAPT_Connector\FASTQ Uploads"
7. Click "Save" to record the settings.
8. ADAPT-CE will now display an initialization key vital to the installation. Please copy/paste this key to a safe and retrievable location as you will need the key in the next installation step.
9. ADAPT-CE will then open a dialog box allowing you to save the installer for the Agendia Service Connector.
10. Select a local drive location on your computer and save the Agendia Service Connector installer.



11. Once the Service Connector Installer is downloaded, navigate to the location of the saved program and initialize the Installer.
    a. Follow the instructions in the installer and click "Next" as prompted.
    b. Select the local drive installation directory.
    c. Enter or paste the initialization key that was provided by ADAPT-CE from Step 8.
    d. Installation will now initiate.
    e. When installation is complete, click "Finish" to exit the Installer.
    f. Upon successful installation, a "currently connected" status will appear in the "Site Connectivity Settings".
    g. The Agendia Service Connector is now ready for use.



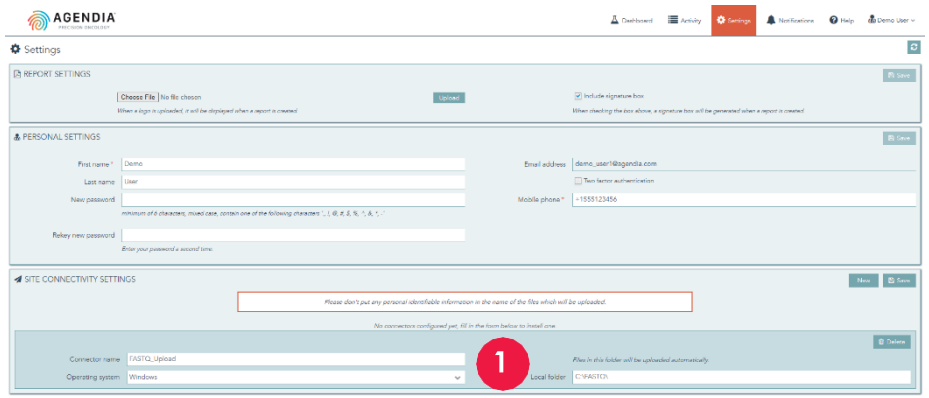
CUSTOMIZING ADAPT-CE REPORTS

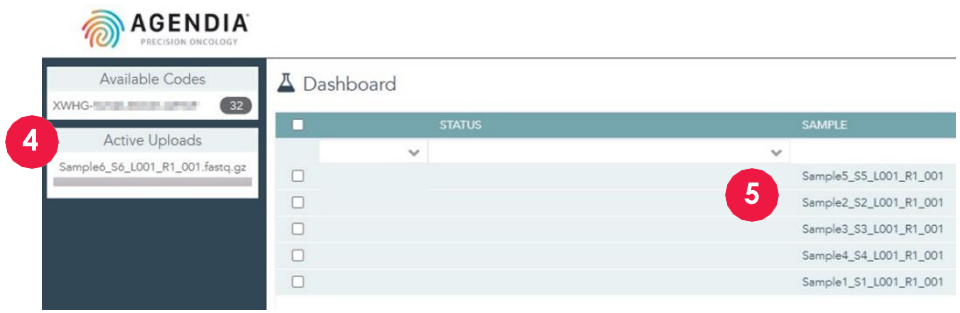
Adding your organization's logo to reports.

1. Log into ADAPT-CE at https://ica.illumina.com/ADAPT-CE
2. Click "Settings" in the top menu bar.
3. In the section titled "Report Settings", click "Choose File" and navigate to the file location of your business logo.
    a. Logo formats must be: JPEG, GIF, BMP or PNG.
    b. Your logo file cannot be larger than 5 megabytes (MB).
4. Click "Upload".
5. Once your logo is uploaded, it will be included in the upper right corner of each report you generate.

Adding an "Authorized Signature" box to Technical Reports.

6. Log into ADAPT-CE at https://ica.illumina.com/ADAPT-CE
7. Click "Settings" in the top menu bar.
8. In the section titled "Report Settings", click the "Include signature box"check box. The signature box will appear in the lower left section of the Technical Report.



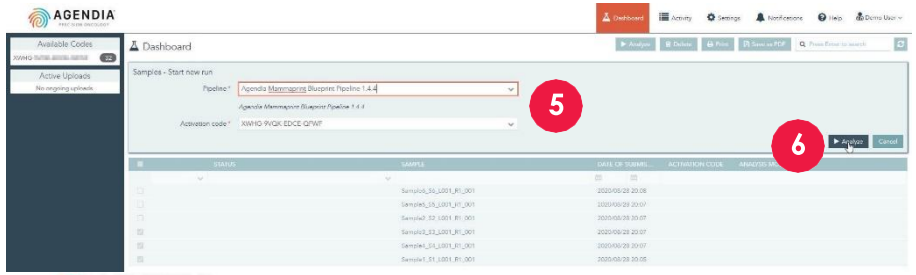


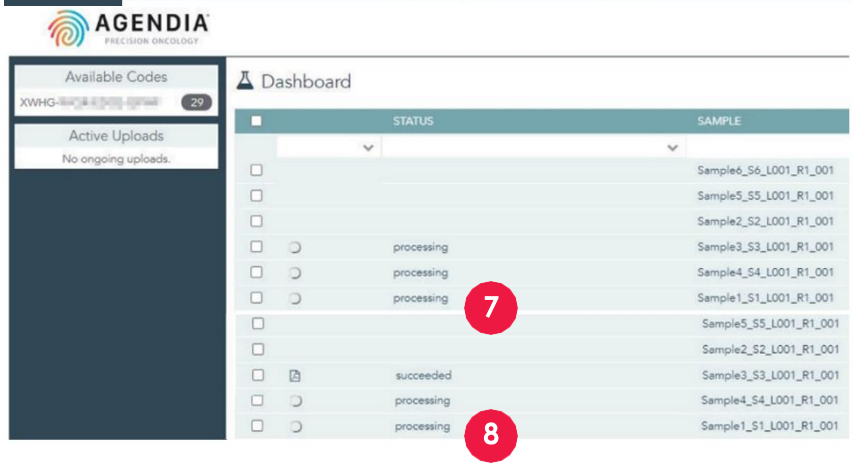
Using ADAPT-CE

UPLOADING FASTQ FILES

- **CAUTION:** To ensure the privacy of your patients, do not include any personally identifying information (PII) in the filenames of your FASTQ files.
- **CAUTION:** The filenames must only contain alphanumeric characters (0-9, a-z, A-Z), and underscore characters (_). File extension must be in lowercased ".fastq.gz" format. E.g., "AbC_123.fastq.gz"
- **CAUTION:** DO NOT alter the contents of your FASTQ files.Doing so may cause incorrect results to be generated or may prevent ADAPT-CE from processing.

1. When ready for uploading, copy the FASTQ file(s) into the directory specified during step 6 of "Installing the Agendia Service Connector".
   a. If you do not see file extensions in your file browser, please contact your IT Department for assistance.
2. The Agendia Service Connector will detect when new FASTQ are present and automatically upload them to ADAPT-CE.
3. Log into ADAPT-CE at https://ica.illumina.com/ADAPT-CE
4. Ongoing uploads are shown on the "Active Uploads"page in ADAPT-CE.
5. Upon a successful upload, the FASTQ will appear on the Dashboard.
6. FASTQs can now be analyzed and generate reports.





Analyzing Data

1. Log into ADAPT-CE at https://ica.illumina.com/ADAPT-CE
2. Click "Dashboard" in the top menu bar.
3. Select FASTQ file(s) you want to analyze by clicking the respective check boxes on the same row as the Sample.
4. Click "Analyze".
5. You will be prompted to enter the "Pipeline" and "Activation code" to set up the analysis settings.
   a. **CAUTION:** Make sure that the Available Codes you select has sufficient remaining reactions for your planned Analysis. If you have insufficient reactions for your planned analysis, you will need to split your batch to conform with remaining kit codes.
6. Once you have confirmed the entries, click "Analyze" to start analysis of the FASTQs.
7. During data analysis, the status field next to the relevant FASTQ files will show as "processing".
8. Upon completion of data analysis, the status field next to the relevant FASTQ files will change to "succeeded".

Downloading Reports

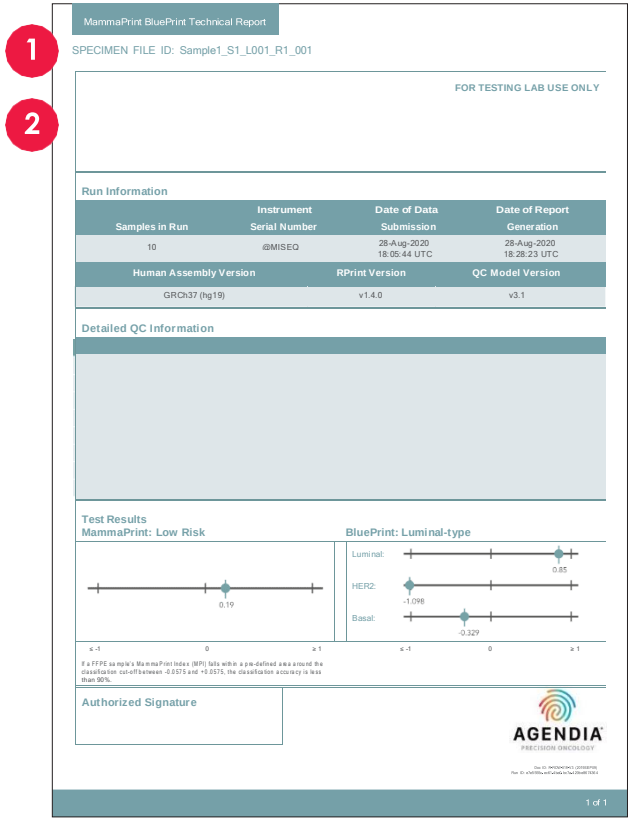
1. Log into ADAPT-CE at https://ica.illumina.com/ADAPT-CE
2. Click on "Dashboard" in the top menu bar.
3. To print reports:
   a. Click the check box next to the file(s) and click "Print".
   b. Your PDF reader software will open the selected file(s).
   c. The Technical Report and Explanation of Results reports can now be printed.
4. To save reports:
   a. Click the check box next to the file(s) and click "Save as PDF".
   b. Your PDF reader software will open the selected file(s).
   c. Save the reports to a directory of your choice.

ADAPT-CE Reports

ADAPT-CE generates two reports:

1. Technical Report
2. Explanation of Results

Reports are combined in a single PDF file for your convenience. Sample reports can be found on our website: www.agendia.com/diagnostic-products/resources.html



Technical Report

The Technical Report contains the following sections:

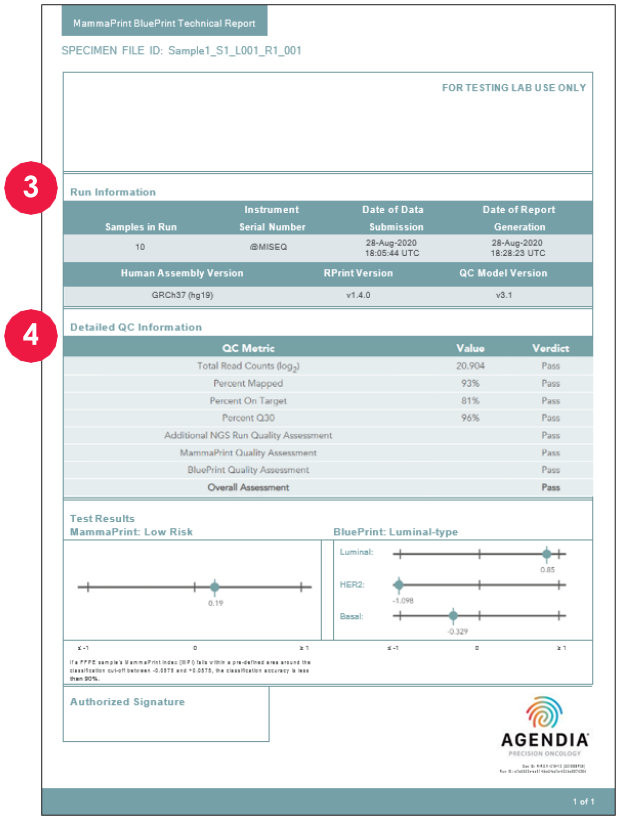
1. Specimen File ID
2. Testing Lab Use Only
3. Run Information
4. Detailed QC Information
5. MammaPrint Test Result
6. BluePrint Test Result

1. SPECIMEN FILE ID

CAUTION: Users are responsible for ensuring that all uploaded files are de-identified. The Specimen File ID is the name of the FASTQ file that was analyzed to generate the Technical Report. To ensure the privacy of your patients DO NOT include any personal identifiable information (PII) in your FASTQ file name, ADAPT-CE will not match the Specimen File ID to any other information.

2. TESTING LAB USE ONLY

This section is intended for the lab to use after they download the document in the case that they would like to add any additional information to the report.



MammaPrint BluePrint Technical Report

SPECIMEN FILE ID: Sample1_S1_L001_R1_001

FOR TESTING LAB USE ONLY

3 Run Information

Samples in Run	Instrument Serial Number	Date of Data Submission	Date of Report Generation
10	@MISEQ	28-Aug-2020 18:05:44 UTC	28-Aug-2020 18:28:23 UTC

Human Assembly Version	RPrint Version	QC Model Version
GRCh37 (hg19)	v1.4.0	v3.1

4 Detailed QC Information

QC Metric	Value	Verdict
Total Read Counts (log_2)	20.904	Pass
Percent Mapped	93%	Pass
Percent On Target	81%	Pass
Percent Q30	96%	Pass
Additional NGS Run Quality Assessment		Pass
MammaPrint Quality Assessment		Pass
BluePrint Quality Assessment		Pass
Overall Assessment		**Pass**

Test Results

MammaPrint: Low Risk

BluePrint: Luminal-type

Authorized Signature

AGENDIA

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3. RUN INFORMATION

This section contains information about the analysis performed by ADAPT-CE. The table below provides additional details:

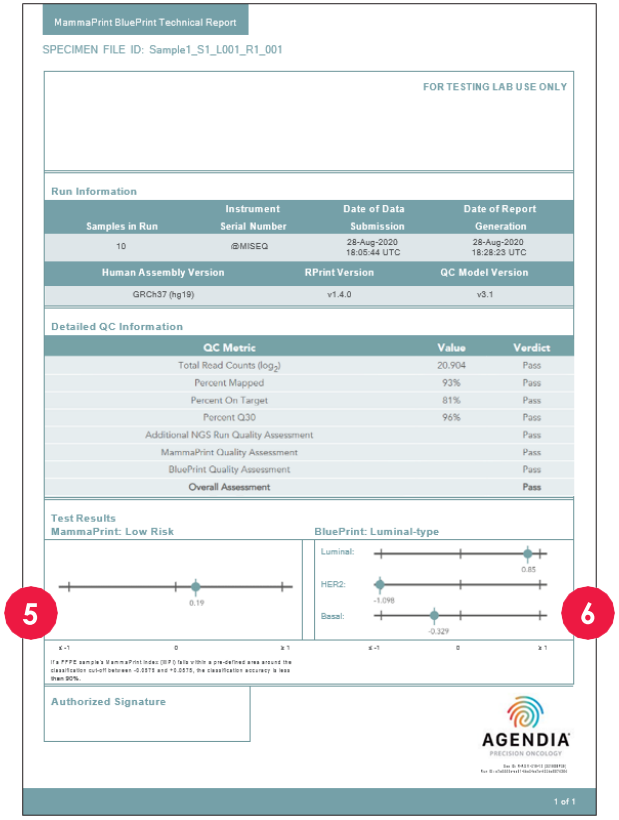
Run Information	Details
Samples in Run	The number of samples in an analysis run
Instrument Serial Number	The serial number of the MiSeq instrument
Date of Data Submission	Date FASTQs are detected and uploaded
Date of Report Generation	Date the reports are analyzed
Human Assembly Version	The version of the human genome used to map the NGS reads.
RPrint Version	The version of the RPrint component of ADAPT-CE
QC Model Version	The version of the QC model within RPrint

4. DETAILED QC INFORMATION

This section contains various quality control (QC) metrics within an individual sample's analysis results. The Total Read Counts, Percent Mapped, Percent On Target and Percent Q30 are commonly used in analysis of RNA sequencing data. The other QC metrics are proprietary to Agendia and are part of the algorithm component of ADAPT-CE.

Note: If any of the above-mentioned QC metrics fail,

- Overall Assessment will display a "**Fail**" verdict.
- Test Results section: "Unable to provide result for this specimen"
- Explanation of Results will not be provided.



MammaPrint BluePrint Technical Report

SPECIMEN FILE ID: Sample1_S1_L001_R1_001

FOR TESTING LAB USE ONLY

Run Information

Samples in Run	Instrument Serial Number	Date of Data Submission	Date of Report Generation
10	@MISEQ	28-Aug-2020 18:05:44 UTC	28-Aug-2020 18:28:23 UTC

Human Assembly Version	RPrint Version	QC Model Version
GRCh37 (hg19)	v1.4.0	v3.1

Detailed QC Information

QC Metric	Value	Verdict
Total Read Counts (log_2)	20.904	Pass
Percent Mapped	93%	Pass
Percent On Target	81%	Pass
Percent Q30	96%	Pass
Additional NGS Run Quality Assessment		Pass
MammaPrint Quality Assessment		Pass
BluePrint Quality Assessment		Pass
Overall Assessment		**Pass**

Test Results

MammaPrint: Low Risk

BluePrint: Luminal-type

Authorized Signature

AGENDIA PRECISION ONCOLOGY

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5. MAMMAPRINT TEST RESULT

The MammaPrint result is provided as a binary result of either "Low Risk" or "High Risk" for risk of recurrence. The prognostic profile (Low Risk, High Risk) of the sample is determined by calculating the MammaPrint Index (MPI) on a scale of -1.000 to +1.000

- High Risk results are those results that are equal to or below 0.000
- Low Risk results are those above 0.000

If the MammaPrint Index (MPI) falls within a pre-defined area around the classification cut-off between -0.058 and +0.058, the classification accuracy is less than 90%.

6. BLUEPRINT TEST RESULT

The BluePrint result is provided as Luminal-type, HER2-type, or Basal-type. Under the BluePrint outcome are graphic scales indicating the BluePrint indices (one for each of the three subtypes), ranging from -1.000 to +1.000

- The subtype with the highest value is the dominant subtype and hence is the outcome of BluePrint. In the case of multiple dominant subtypes, the result will display: "Mixed subtype".


Explanation of Results: MammaPrint BluePrint

SPECIMEN FILE ID: Sample1_S1_L001_R1_001

LOW RISK LUMINAL-TYPE (A)

MammaPrint Risk of Recurrence Result: LOW RISK

MammaPrint Index: 0.211

Average 10-Year Risk of Recurrence if untreated:[4] 10%

BluePrint Molecular Subtype Result:[2] LUMINAL-TYPE

Predicted Risk of Recurrence Without Adjuvant Systemic Treatment[1]

Risk of Recurrence (%)

Years

The integration of clinical risk assessment with MammaPrint results can help refine an individual's prognosis to help better guide the most appropriate treatment strategy. The percentage of patients without distant recurrence at 5 years (DMFS) shown in the diagrams below were observed in the MINDACT trial (clinical risk can be determined by utilizing the clinical risk algorithm on page 2).

Clinical Pathological Low Risk/MammaPrint Low Risk[3]

% of patients without metastasis at 5 years (Distant Metastasis Free Survival)

5 Years Endocrine Therapy Alone (if applicable) 97.6%

Clinical Pathological High Risk/MammaPrint Low Risk[3]

% of patients without metastasis at 5 years (Distant Metastasis Free Survival)

Endocrine Therapy Alone 94.4%

Endocrine Therapy + Chemotherapy 95.9%

% of patients without metastasis at 5 years

1.5% non-significant additional benefit of CT (p-value=0.27)[5]

AGENDIA PRECISION ONCOLOGY

A MammaPrint Low Risk result does not guarantee that cancer will not recur. A High Risk result does not guarantee that cancer will recur. Individual results may vary. MammaPrint results should be taken in the context of other relevant clinico-pathological factors and standard practice of medicine.

[5] A p-value is the likelihood of obtaining a statistical result by chance, assuming there is no difference between the treatments being investigated. The lower the p-value the less likely the result happened by chance, and the more likely the result can be attributed to the drug being tested.

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Explanation of Results (EoR)

The Explanation of Results is provided as a tool to supplement the results provided in the Technical Report described above. The Explanation of Results explains the MammaPrint and BluePrint results in the context of published clinical data.

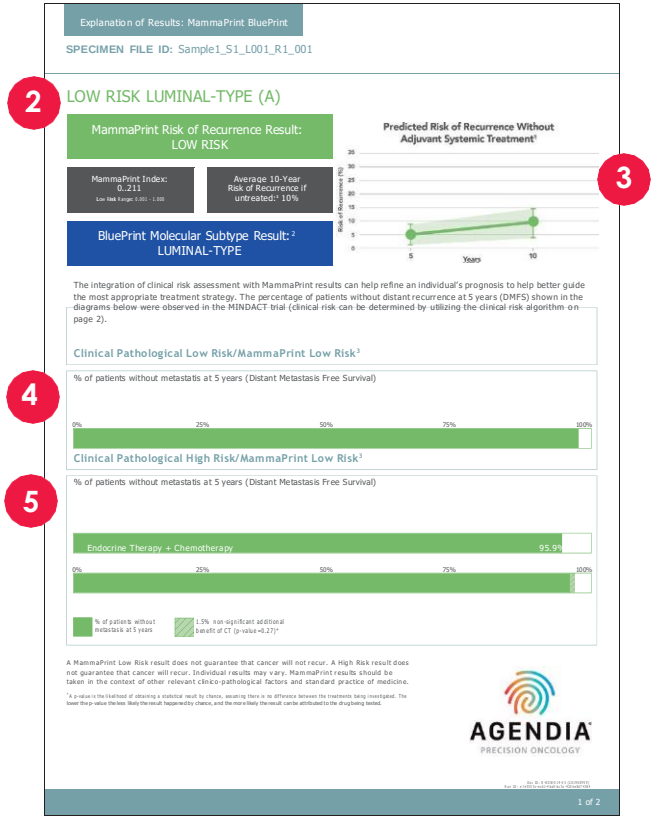
Furthermore, the integration of clinical risk assessment with MammaPrint results can help refine an individual's prognosis to help better guide the most appropriate treatment management strategy. The percentage of patients without distant recurrence at 5 years (DMFS) shown in the diagrams in sections 5 and 6 of the EoR were observed in the MINDACT trial[3,6].

The EoR is a two-page document that contains the following key sections:

1. Specimen File ID
2. Summary of Individual Test Results
3. Predicted Result without Systemic Treatment
4. Data from the MINDACT Trial for Concordant Classification
5. Data from the MINDACT Trial for Discordant Classification
6. Clinical Risk Assessment Table
7. BluePrint Molecular Subtyping Results

1. SPECIMEN FILE ID

CAUTION: Users are responsible for ensuring that all uploaded files are de-identified. The Specimen File ID is the name of the FASTQ file that was analyzed to generate the Technical Report. To ensure the privacy of your patients DO NOT include any PI in your FASTQ file name. ADAPT-CE will not match the Specimen File ID to any other information.


Explanation of Results: MammaPrint BluePrint

SPECIMEN FILE ID: Sample1_S1_L001_R1_001

2

LOW RISK LUMINAL-TYPE (A)

MammaPrint Risk of Recurrence Result: LOW RISK

MammaPrint Index: 0..211

Average 10-Year Risk of Recurrence if untreated: 10%

BluePrint Molecular Subtype Result: LUMINAL-TYPE

3

Predicted Risk of Recurrence Without Adjuvant Systemic Treatment

Risk of Recurrence (%)

Years

The integration of clinical risk assessment with MammaPrint results can help refine an individual's prognosis to help better guide the most appropriate treatment strategy. The percentage of patients without distant recurrence at 5 years (DMFS) shown in the diagrams below were observed in the MINDACT trial (clinical risk can be determined by utilizing the clinical risk algorithm on page 2).

Clinical Pathological Low Risk/MammaPrint Low Risk

4

% of patients without metastatis at 5 years (Distant Metastasis Free Survival)

0% 25% 50% 75% 100%

Clinical Pathological High Risk/MammaPrint Low Risk

5

% of patients without metastatis at 5 years (Distant Metastasis Free Survival)

Endocrine Therapy + Chemotherapy 95.9%

0% 25% 50% 75% 100%

% of patients without metastasis at 5 years

1.5% non-significant additional benefit of CT (p-value=0.27)

A MammaPrint Low Risk result does not guarantee that cancer will not recur. A High Risk result does not guarantee that cancer will recur. Individual results may vary. MammaPrint results should be taken in the context of other relevant clinico-pathological factors and standard practice of medicine.

AGENDIA PRECISION ONCOLOGY

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2. SUMMARY OF INDIVIDUAL TEST RESULTS

This section summarizes the MammaPrint and BluePrint result from the Technical Report

- MammaPrint Risk of Recurrence Result
- MammaPrint Index
- Average 10-year risk of recurrence for lymph node negative (LN0) patients with the same risk result if they received no endocrine therapy or chemotherapy[1] (untreated).
- BluePrint Molecular Subtype Result

3. PREDICTED RESULT WITHOUT SYSTEMIC TREATMENT

This section provides the predicted average risk of recurrence without adjuvant treatment at 5 and 10 years, with 95% confidence intervals shaded in light green.

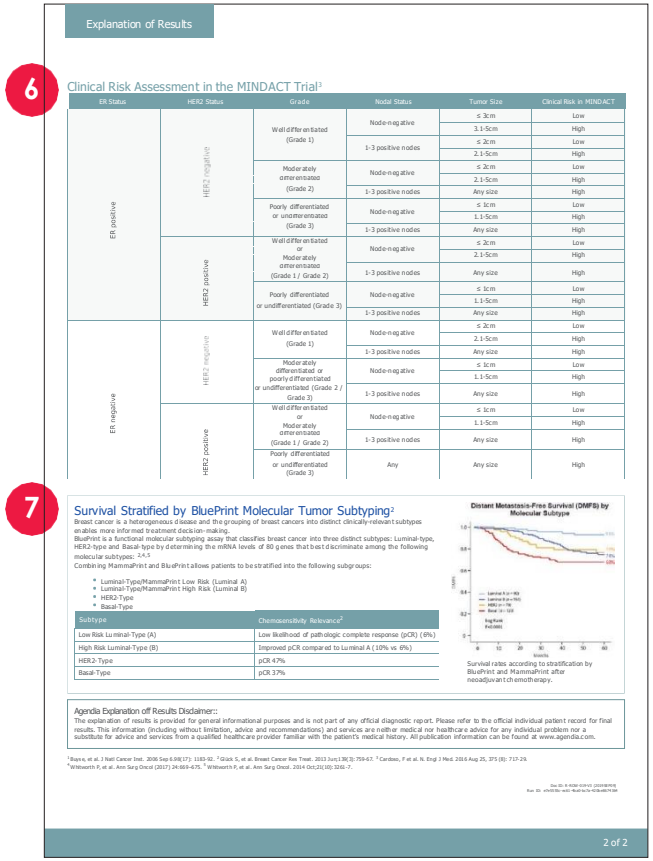
4. DATA FROM THE MINDACT TRIAL FOR CONCORDANT CLASSIFICATION WITH SYSTEMIC TREATMENT

This section provides the percentage of patients without metastasis at 5-years (Distant Metastasis Free Survival endpoint) with concordant classification (Clinically High and MammaPrint High Risk or Clinically Low and MammaPrint Low Risk).

- For patients with a MammaPrint Low Risk result, this section provides the percentage of patients without metastasis at 5-years that had Endocrine Therapy alone that were classified as Clinically Low Risk and MammaPrint Low Risk[3].
- For patients with a MammaPrint High Risk result, this section provides the percentage of patients without metastasis at 5-years that had Endocrine Therapy and Chemotherapy that were classified as Clinically High Risk and MammaPrint High Risk[3].

5. DATA FROM THE MINDACT TRIAL FOR DISCORDANT CLASSIFICATION

This section shows the percentage of patients without metastasis at 5-years (Distant Metastasis Free Survival endpoint) with discordant classification (Clinically High and MammaPrint Low Risk or Clinically Low and MammaPrint High Risk).



Explanation of Results

6 Clinical Risk Assessment in the MINDACT Trial[3]

ER Status	HER2 Status	Grade	Nodal Status	Tumor Size	Clinical Risk in MINDACT
ER positive	HER2 negative	Well differentiated (Grade 1)	Node-negative	≤ 3cm	Low
				3.1-5cm	High
			1-3 positive nodes	≤ 2cm	Low
				2.1-5cm	High
		Moderately differentiated (Grade 2)	Node-negative	≤ 2cm	Low
				2.1-5cm	High
			1-3 positive nodes	Any size	High
		Poorly differentiated or undifferentiated (Grade 3)	Node-negative	≤ 1cm	Low
				1.1-5cm	High
			1-3 positive nodes	Any size	High
	HER2 positive	Well differentiated or Moderately differentiated (Grade 1 / Grade 2)	Node-negative	≤ 2cm	Low
				2.1-5cm	High
			1-3 positive nodes	Any size	High
		Poorly differentiated or undifferentiated (Grade 3)	Node-negative	≤ 1cm	Low
				1.1-5cm	High
			1-3 positive nodes	Any size	High
ER negative	HER2 negative	Well differentiated (Grade 1)	Node-negative	≤ 2cm	Low
				2.1-5cm	High
			1-3 positive nodes	Any size	High
		Moderately differentiated or poorly differentiated or undifferentiated (Grade 2 / Grade 3)	Node-negative	≤ 1cm	Low
				1.1-5cm	High
			1-3 positive nodes	Any size	High
	HER2 positive	Well differentiated or Moderately differentiated (Grade 1 / Grade 2)	Node-negative	≤ 1cm	Low
				1.1-5cm	High
			1-3 positive nodes	Any size	High
		Poorly differentiated or undifferentiated (Grade 3)	Any	Any size	High

7 Survival Stratified by BluePrint Molecular Tumor Subtyping[2]

Breast cancer is a heterogeneous disease and the grouping of breast cancers into distinct clinically-relevant subtypes enables more informed treatment decision-making.
BluePrint is a functional molecular subtyping assay that classifies breast cancer into three distinct subtypes: Luminal-type, HER2-type and Basal-type by determining the mRNA levels of 80 genes that best discriminate among the following molecular subtypes: [2,4,5]
Combining MammaPrint and BluePrint allows patients to be stratified into the following subgroups:

- Luminal-Type/MammaPrint Low Risk (Luminal A)
- Luminal-Type/MammaPrint High Risk (Luminal B)
- HER2-Type
- Basal-Type

Subtype	Chemosensitivity Relevance[2]
Low Risk Luminal-Type (A)	Low likelihood of pathologic complete response (pCR) (6%)
High Risk Luminal-Type (B)	Improved pCR compared to Luminal A (10% vs 6%)
HER2-Type	pCR 47%
Basal-Type	pCR 37%

Distant Metastasis-Free Survival (DMFS) by Molecular Subtype

Survival rates according to stratification by BluePrint and MammaPrint after neoadjuvant chemotherapy.

Agendia Explanation off Results Disclaimer::
The explanation of results is provided for general informational purposes and is not part of any official diagnostic report. Please refer to the official individual patient record for final results. This information (including without limitation, advice and recommendations) and services are neither medical nor healthcare advice for any individual problem nor a substitute for advice and services from a qualified healthcare provider familiar with the patient's medical history. All publication information can be found at www.agendia.com.

[1] Buyse, et al. J Natl Cancer Inst. 2006 Sep 6;98(17): 1183-92. [2] Glück S, et al. Breast Cancer Res Treat. 2013 Jun;138(3):759-67. [3] Cardoso, F et al. N. Engl J Med. 2016 Aug 25, 375 (8): 717-29.
[4] Whitworth P, et al. Ann Surg Oncol (2017) 24:669-675. [5] Whitworth P, et al. Ann Surg Oncol. 2014 Oct;21(10):3261-7.

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For patients with a MammaPrint Low Risk result, this section provides the percentage of patients without metastasis at 5-years that had Endocrine Therapy alone compared to those that received Endocrine Therapy and Chemotherapy that were classified as Clinically High Risk and MammaPrint Low Risk in the MINDACT Study[3,6].

For patients with a MammaPrint High Risk result, this section provides the percentage of patients without metastasis at 5-years that had Endocrine Therapy alone compared to those, that received Endocrine Therapy and Chemotherapy that were classified as Clinically Low Risk and MammaPrint High Risk in the MINDACT Study[3,6].

Note: No sub-analysis has been performed on individual molecular subtypes. The data refers to the randomized cohort which includes all molecular subtypes. There is no adequate data to support treatment of MammaPrint Low Risk Basal-type tumors or MammaPrint Low Risk HER2-Type with endocrine therapy alone.

6. CLINICAL RISK ASSESSMENT TABLE

As referenced in the supplementary material of the MINDACT publication (see Figure 12), this table can help determine the clinical risk results as defined in the MINDACT trial (Clinically High or Low Risk)[3,6].

Clinical risk classification in MINDACT was carried out using the modified version of Adjuvant! Online (version 8.0)[3,6].

7. BLUEPRINT MOLECULAR SUBTYPING RESULTS

This section provides results of study showing chemosensitivity for patients in a neoadjuvant setting based on molecular subtype [2,4,5].

Troubleshooting

- The following Troubleshooting points pertain to topics related to ADAPT-CE setup and operation.
- For an additional list of troubleshooting topics, please refer to the Help tab at the top right of the ADAPT-CE Interface.

Problem	Solution
Forgot your password to ADAPT-CE.	Go to the login screen from https://ica.illumina.com/ADAPT-CE. Click on the "Forgot password?" link and follow the instructions provided. If you still are unable to login, contact NGS.support@agendia.com for additional assistance.
Experiencing issues with setting up the Agendia Service Connector.	Go to the "Settings" section of ADAPT-CE and click "Delete" on the connector you are having issues with. Ensure a local folder on the computer is established and follow steps to install another uniquely named connector.
Files are not being uploaded to ADAPT-CE via the Agendia Service Connector.	Go to the "Settings" section of ADAPT-CE and ensure that the "Local folder" listed for the Agendia Service Connector matches the directory where the FASTQ files are.
Pages in ADAPT-CE are not functioning as expected.	Click the "Refresh" button on the page. If the problem persists, contact NGS.support@agendia.com.
Duplicate FASTQ files appear within ADAPT-CE	Make sure that you upload your FASTQ file only once when using the Agendia Secure Connector. In the event you duplicate an upload, navigate to the Agendia Secure Connector upload folder, delete the duplicates and reupload a single file.
The result for a sample only includes aTechnical Report and does not include an Explanation of Results (EoR) document.	Check the verdict for the Overall Assessment. If it says "Fail", then no Explanation of Results (EoR) is generated for the sample.
You are unable to print or save reports for a sample.	Ensure that the status field next to the sample on the "Dashboard" page says "succeeded" and that a PDF icon is shown.
FASTQ files remain hanging underneath "Active Uploads" after deleting the FASTQ file from the connector or after successful FASTQ file upload into the Dashboard.	Click the "Abort Data Transfer Functionality" button within "Active Uploads" for the hanging FASTQ file that you wish to remove.

Miscellaneous

SECURITY

Agendia has established a Privacy Policy and Terms of Service available on our website at www.agendia.com to inform you of the specific practices and guidelines that help ensure the security and confidentiality of personal information that you may provide.

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BROWSER SESSION TIMEOUT AND SYMBOLS

For security purposes, after 15 minutes of inactivity in the browser, the software will automatically end your session and sign you out. A warning message will be displayed prior to signing you out, giving you the option to stay signed in.

Symbol	Title of Symbol	Description of Symbol
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.

If you have any questions regarding this product, please contact NGS.Support@agendia.com or by telephone at +31 (0) 20 462 1510, Monday to Friday from 08:30 to 17:00 (GMT/UTC +1).

References

1. Buyse, et al. J Natl Cancer Inst. 2006 Sep 6.98(17): 1183-92
2. Glück S, et al. Breast Cancer Res Treat. 2013 Jun;139(3):759-67
3. Cardoso, F et al. N. Engl J Med. 2016 Aug 25, 375 (8): 717-29
4. Whitworth P, et al. Ann Surg Oncol. (2017) 24:669–675
5. Whitworth P, et al. Ann Surg Oncol. 2014 Oct;21(10):3261-7
6. Piccart M, et al. Lancet Oncol. 2021 Apr;22(4):476-488

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