

IHE International Conformity Assessment Program - Test Report



IHE-ATL-001
IHE International Conformity
Assessment Program
IHE-CAS-2: 2015

April, 22nd 2015



The product and version documented in this report was tested by an IHE International-authorized testing laboratory in accordance with ISO/IEC 17025 requirements and the IHE Conformity Assessment Scheme (IHE-CAS) to demonstrate conformance with the IHE International profiles and actors identified in this report.

It provides a third-party conformity assessment of the product's adherence to one or more IHE Profiles. It demonstrates that the product is capable of assisting healthcare providers and hospitals in meeting requirements for clinical integration.

Testing was conducted as specified in the IHE-CAS-1 and IHE-CAS-2 documents. Testing consisted of observed demonstrations in a controlled location under normal operating conditions and using approved test tools. Test efforts also included review of test tool results, self-attestation materials and, where applicable, interoperability testing files and audit logs. Testing was constrained to the use of the IHE International technical frameworks specified in IHE-CAS-2 at the time of testing. Any exceptions to these requirements are noted within this test report, when applicable.

About KEREVAL Health Lab and IHE-Europe

KEREVAL Health Lab is authorized by IHE International (Authorization #: IHE-ATL-001) in conjunction with IHE-Europe, an IHE Deployment Committee, to perform testing of health information technology to IHE International profiles and actors, as specified in the IHE technical frameworks.

For comments or suggestions on this Conformity Assessment program, please contact IHE-Europe: info@deployement.ihe.net



Profiles/Actors Tested for Conformity Assessment

The IHE Authorized Testing Laboratory determined that

GE XDS Registry / 2.11 provided for conformity assessment by

GE Healthcare located at Nightingales Lane, Chalfont St Giles, HP8 4SP, UNITED KINGDOM

successfully demonstrated compliance to the selected profile/actor pairs for the IHE International Conformity Assessment Program per IHE-CAS-1 **2015** and IHE-CAS-2 **2015**.

The System Under Test was made available for test on April, 22rd 2015.

Tests were executed between **April**, **22**rd **2015** and **April**, **24**th **2015** at LUXEXPO, 10 circuit de la Foire Internationale, L-1347 Luxembourg-Kirchberg, LUXEMBOURG.

| IHE Profile | Actor and <i>Options</i> | Test Result | | |
|--|--------------------------------|-------------|--|--|
| IT —Infrastructure | | | | |
| IHE-CT | Time Client: | | | |
| Consistent Time enables system clocks and time stamps of computers in a network to be synchronized (median error less than 1 second). | - No Option | Pass | | |
| IHE-ATNA | Secure Application: | | | |
| Audit Trail and Node Authentication <i>establishes the characteristics of a Basic Secure Node.</i> | - No Option | Pass | | |
| IHE-XDS.b Cross-Enterprise Document Sharing enables a number of healthcare delivery organization to share clinical records in the form of documents | Document Registry: - No option | Pass | | |



Additional Software Required for Testing

The following additional software/options were required by **GE Healthcare GE XDS Registry 2.11** to assist in demonstrating compliance with the associated conformance requirements by providing the specified functionality:

| Software Product and Developer | Associated Profiles/Actors | Functionality Provided | |
|--------------------------------|-------------------------------|------------------------|--|
| None | - | - | |



Report Summary

KEREVAL Health Lab, an IHE International Authorized Testing Laboratory has reviewed and confirms that **GE Healthcare GE XDS Registry 2.11** successfully passed the test scripts identified in this report through attestation, observed demonstration, review of audit logs, and/or interoperability file validations. Testing was conducted using IHE-CAS-2:**2015** testing processes based on ISO/IEC 17025. All test results documented in this report including the exceptions mentioned, are considered formal test results. This test results summary is authorized by:

Eric POISEAU KEREVAL Health Lab Manager

Test Lab Authorized Representative Function/Title

November 16th 2015

Signature and Date

A detailed test report is kept by the IHE Authorized Testing Laboratory and IHE International Conformity Assessment Committee and is available upon requests to these entities.

Please visit http://www.ihe.net/Conformity_Assessment.aspx for the most current information about this IHE Conformity Assessment program.

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About KEREVAL Health Lab

KEREVAL Health Lab offers third-party testing of health IT products. KEREVAL Health Lab is an ISO/IEC 17025:2005 accredited organization. Visit http://www.kereval.com for more information.

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Appendix A – Testing Comments

This Appendix documents or references any exceptions identified during testing.

| IHE Profile | Actor and Required Options | Test Cases Comments | Test Tools | |
|------------------------------|---------------------------------------|------------------------|--|--|
| IT-Infrastructure / rev 11.0 | | | | |
| IHE-CT | Time Client: - No Option | No exception | None | |
| IHE-ATNA | Secure Application: - No option | No exception | Gazelle ATNA Tools (4.7.12) Syslog Collector (2.1) | |
| IHE-XDS-b | Document Registry: - No option | No exception | XDS Tools 2 (200) | |

Additional Software Required for Testing with Exceptions:

| Software Product and Developer | Associated Profiles/Actors | Exception identified during testing |
|--------------------------------|----------------------------|-------------------------------------|
| None | None | None |