ONC HIT Certification Program Test Results Summary for 2014 Edition EHR Certification

Part 1: Product and Developer Information

1.1 Certified Product Information

Product Name:	AXEIUM
Product Version:	EHR
Domain:	Ambulatory
Test Type:	Complete

1.2 Developer/Vendor Information

Developer/Vendor Name:	Brilogy Corporation
Address:	PO Box 1800, Costa Mesa, CA 92628
Website:	AXEIUM.com
Email:	milton.allione@brilogy.com
Phone:	714.609.9900
Developer/Vendor Contact:	Milton Allione

Part 2: ONC-Authorized Certification Body Information

2.1 ONC-Authorized Certification Body Information

ONC-ACB Name:	SLI Compliance	
Address:	4720 Independence St.	
	Wheat Ridge, Colorado 80033	
Website:	www.slicompliance.com	
Email:	acb@slicompliance.com	
Phone:	844-754-8683	
ONC-ACB Contact:	Lesley Hoppert, Certification Manager	

This test results summary is approved for public release by the following ONC-Authorized Certification Body Representative:

Lesley Hoppert	
ONC-ACB Authori	ized Representative
Lerley Hopper	-
Carry in the	3/20/2019

Certification Manager Function/Title

Signature and Date

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
🗌 (a)(1)	🗌 (a)(17)	□ (d)(5)	□ (d)(9)
🗌 (a)(6)	□ (b)(5)*	□ (d)(6)	□ (f)(1)
🗌 (a)(7)	□ (d)(1)	□ (d)(8)	

*Gap certification allowed for Inpatient setting only

 \boxtimes No gap certification

2.3 Inherited Certification

The following identifies criterion or criteria certified via inherited certification

		§17(0.314	
🗌 (a	a)(1)	🗌 (a)(14)	□ (c)(3)	□ (f)(1)
🗌 (a	a)(2)	🗌 (a)(15)	□ (d)(1)	□ (f)(2)
🗌 (a	a)(3)	□ (a)(16) <i>Inpt. only</i>	□ (d)(2)	□ (f)(3)
🗌 (a	a)(4)	(a)(17) Inpt. only	□ (d)(3)	☐ (f)(4) Inpt. only
🗌 (a	a)(5)	□ (b)(1)	□ (d)(4)	(f)(5) Optional &
🗌 (a	a)(6)	(b)(2)	□ (d)(5)	└── Amb. only
🗌 (a	a)(7)	□ (b)(3)	□ (d)(6)	┌┐ (f)(6) <i>Optional</i> &
🗌 (a	a)(8)	□ (b)(4)	□ (d)(7)	└── Amb. only
🗌 (a	a)(9)	🗌 (b)(5)	□ (d)(8)	□ (g)(1)
🗌 (a	a)(10)	(b)(6) Inpt. only	☐ (d)(9) Optional	□ (g)(2)
🗌 (a	a)(11)	□ (b)(7)	🗌 (e)(1)	□ (g)(3)
🗌 (a	a)(12)	□ (c)(1)	(e)(2) Amb. only	□ (g)(4)
🗌 (a	a)(13)	□ (c)(2)	(e)(3) <i>Amb. only</i>	

 \boxtimes No inherited certification

Part 3: NVLAP-Accredited Testing Laboratory Information

Report Number: 60.2

Test Date(s): 03/16/2015-03/18/2015, 03/20/2015, 03/23/2015-03/24/2015

3.1 NVLAP-Accredited Testing Laboratory Information

ATL Name:	SLI Compliance	
Accreditation Number:	200733-0	
Address:	4720 Independence St Wheat Ridge, CO 80033 USA	
Website:	http://www.SLIcompliance.com	
Email:	info@sliglobalsolutions.com	
Phone:	303.215.5853	
ATL Contact:	Dustin George	
For more information on scope of accreditation, please reference <u>http://ts.nist.gov/standards/scopes/2007330.htm</u>		

Part 3 of this test results summary is approved for public release by the following Accredited Testing Laboratory Representative:

Dustin George
ATL Authorized Representative
Detin
3/14/2019

Health IT Test Lab Manager Function/Title

Signature and Date

3.2 Test Information

3.2.1 Additional Software Relied Upon for Certification

Additional Software	Applicable Criteria	Functionality provided by Additional Software
MDToolbox	В3	e-Prescribinh Web Services
MDToolbox	B1, B2	Direct Messaging Services
HealthVault	E3	Direct Messaging
MdToolbox		Direct Messaging
HealthVault	E3	(HV is sending; MDTB receiving)

□ No additional software required

3.2.2 Test Tools

Tes	t Tool	Version
\square	Cypress 2.6.0	
\square	ePrescribing Validation Tool	1.0.5
	HL7 CDA Cancer Registry Reporting Validation Tool	
	HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	
	HL7 v2 Immunization Information System (IIS) Reporting Validation Tool 1.8.2	
\square	HL7 v2 Laboratory Results Interface (LRI) Validation Tool	1.7.2
\square	HL7 v2 Syndromic Surveillance Reporting Validation Tool 1.7.2	
	Transport Testing Tool	180
	Direct Certificate Discovery Tool	3.0.3

□ No test tools required

3.2.3 Test Data

- Alteration (customization) to the test data was necessary and is described in Appendix [*insert appendix letter*]
- ☑ No alteration (customization) to the test data was necessary

3.2.4 Standards

3.2.4.1 Multiple Standards Permitted

The following identifies the standard(s) that has been successfully tested where more than one standard is permitted

Criterion #	Standard Successfully Tested		
(a)(8)(ii)(A)(2)	x §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	 §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide 	
(a)(13)	§170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	§170.207(j) HL7 Version 3 Standard: Clinical Genomics; Pedigree	

Criterion #	Standard Successfully Tested		
(a)(15)(i)	 §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain 	 §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide 	
(a)(16)(ii)	§170.210(g) Network Time Protocol Version 3 (RFC 1305)	§170. 210(g) Network Time Protocol Version 4 (RFC 5905)	
(b)(2)(i)(A)	 §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10- CM) for the indicated conditions 	 §170.207(a)(3) IHTSDO SNOMED CT[®] International Release July 2012 and US Extension to SNOMED CT[®] March 2012 Release 	
(b)(7)(i)	 §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10- CM) for the indicated conditions 	 §170.207(a)(3) IHTSDO SNOMED CT[®] International Release July 2012 and US Extension to SNOMED CT[®] March 2012 Release 	
(e)(1)(i)	 Annex A of the FIPS Publication 140-2 AES-256 SHA-256 		
(e)(1)(ii)(A)(2)	Signature State Stat	 §170. 210(g) Network Time Protocol Version 4 (RFC 5905) 	
(e)(3)(ii)	 Annex A of the FIPS Publication 140-2 AES-256 SHA-256 		
Common MU Data Set (15)	 §170.207(a)(3) IHTSDO SNOMED CT[®] International Release July 2012 and US Extension to SNOMED CT[®] March 2012 Release 	§170.207(b)(2) The code set specified at 45 CFR 162.1002(a)(5) (HCPCS and CPT-4)	

None of the criteria and corresponding standards listed above are applicable

3.2.4.2 Newer Versions of Standards

The following identifies the newer version of a minimum standard(s) that has been successfully tested

Newer Versi	on	Applicable Criteria

 \boxtimes No newer version of a minimum standard was tested

3.2.5 Optional Functionality

Criterion #	Optional Functionality Successfully Tested
🗌 (a)(4)(iii)	Plot and display growth charts
□ (b)(1)(i)(B)	Receive summary care record using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
□ (b)(1)(i)(C)	Receive summary care record using the standards specified at §170.202(b) and (c) (SOAP Protocols)
□ (b)(2)(ii)(B)	Transmit health information to a Third Party using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
□ (b)(2)(ii)(C)	Transmit health information to a Third Party using the standards specified at §170.202(b) and (c) (SOAP Protocols)
□ (f)(3)	Ambulatory setting only – Create syndrome-based public health surveillance information for transmission using the standard specified at §170.205(d)(3) (urgent care visit scenario)
Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(3) (45 CFR162.1002(a)(4): Code on Dental Procedures and Nomenclature)
Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(4) (45 CFR162.1002(c)(3): ICD-10-PCS)

☑ No optional functionality tested

3.2.6 2014 Edition Certification Criteria* Successfully Tested

	0	Ver	sion			Ver	sion
	Criteria #	TP* *	TD***		Criteria #	ТР	TD
\square	(a)(1)	1.3	1.5	\boxtimes	(c)(3)	1.11	
\boxtimes	(a)(2)	1.2		\square	(d)(1)	1.2	
	(a)(3)	1.2	1.4		(d)(2)	1.6	
	(a)(4)	1.4	1.3	\square	(d)(3)	1.3	
	(a)(5)	1.4	1.3		(d)(4)	1.3	
\square	(a)(6)	1.3	1.4	\square	(d)(5)	1.2	
	(a)(7)	1.3	1.3	\boxtimes	(d)(6)	1.2	
	(a)(8)	1.2			(d)(7)	1.2	
\square	(a)(9)	1.3	1.3		(d)(8)	1.2	
	(a)(10)	1.2	1.4		(d)(9) Optional		
\square	(a)(11)	1.3		\boxtimes	(e)(1)	1.9	1.5
	(a)(12)	1.3		\boxtimes	(e)(2) Amb. only	1.2	1.6
\square	(a)(13)	1.2		\boxtimes	(e)(3) Amb. only	1.3	
\square	(a)(14)	1.2		\boxtimes	(f)(1)	1.2	1.2
	(a)(15)	1.5		\boxtimes	(f)(2)	1.3	
	(a)(16) Inpt. only			\boxtimes	(f)(3)	1.3	
	(a)(17) Inpt. only				(f)(4) Inpt. only		
\boxtimes	(b)(1)	1.7	1.4		(f)(5) Optional &		
\boxtimes	(b)(2)	1.4	1.6		Amb. only		
\boxtimes	(b)(3)	1.4			(f)(6) Optional &		
\boxtimes	(b)(4)	1.3	1.4		Amb. only		
\boxtimes	(b)(5)	1.4			(g)(1)		
	(b)(6) Inpt. only			\boxtimes	(g)(2)	1.9	2.0
\boxtimes	(b)(7)	1.4	1.7	\square	(g)(3)	1.4	
\boxtimes	(c)(1)	1.11		\boxtimes	(g)(4)	1.2	
\boxtimes	(c)(2)	1.11					

*For a list of the 2014 Edition Certification Criteria, please reference <u>http://www.healthit.gov/certification</u> (navigation: 2014 Edition Test Method)

**Indicates the version number for the Test Procedure (TP)

***Indicates the version number for the Test Data (TD)

3.2.7 2014 Clinical Quality Measures*

Type of Clinical Quality Measures Successfully Tested:

- Ambulatory
- Inpatient
- □ No CQMs tested

*For a list of the 2014 Clinical Quality Measures, please reference <u>http://www.cms.gov</u> (navigation: 2014 Clinical Quality Measures)

			Ambulate	ory CQMs			
CMS I	D Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
2 🛛	4	☐ 90		□ 136		155	
22		🛛 117	3	137		☐ 156	
50		🛛 122	3	138		157	
52		123		139		158	
56		🛛 124	3	140		☐ 159	
61		🛛 125	3	141		☐ 160	
62		126		142		☐ 161	
64		127		143		163	
⊠ 65	4	128		144		164	
66		□ 129		145		⊠ 165	3
8 🛛	4	130		146		🖾 166	4
⊠ 69	3	131		147		167	
74		132		148		☐ 169	
⊠ 75	3	133		149		177	
77		134		153		179	
82		135		154		182	

			Inpatier	nt CQMs			
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
9		71		☐ 107		172	
26		72		☐ 108		178	
30		73		☐ 109		185	
31		91		☐ 110		188	
32		□ 100		111		190	
53		☐ 102		113			
55		104		114			

				Inpatier	nt CQMs			
CMS	S ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
	60		105		171			

3.2.8 Automated Numerator Recording and Measure Calculation

3.2.8.1 Automated Numerator Recording

Automa	Automated Numerator Recording Successfully Tested						
🗌 (a)(1)	🗌 (a)(9)	🗌 (a)(16)	🗌 (b)(6)				
🗌 (a)(3)	🗌 (a)(11)	🗌 (a)(17)	🗌 (e)(1)				
🗌 (a)(4)	🗌 (a)(12)	□ (b)(2)	🗌 (e)(2)				
🗌 (a)(5)	🗌 (a)(13)	🗌 (b)(3)	🗌 (e)(3)				
🗌 (a)(6)	🗌 (a)(14)	□ (b)(4)	-				
🗌 (a)(7)	🗌 (a)(15)	🗌 (b)(5)					

☑ Automated Numerator Recording was not tested

3.2.8.2 Automated Measure Calculation

Automa	Automated Numerator Recording Successfully Tested						
🖾 (a)(1)	🖾 (a)(9)	🗌 (a)(16)	🗌 (b)(6)				
🖾 (a)(3)	🖾 (a)(11)	🗌 (a)(17)	🖾 (e)(1)				
🖾 (a)(4)	🖾 (a)(12)	⊠ (b)(2)	⊠ (e)(2)				
🖾 (a)(5)	🖾 (a)(13)	⊠ (b)(3)	⊠ (e)(3)				
🖾 (a)(6)	🖾 (a)(14)	⊠ (b)(4)					
🖾 (a)(7)	🖾 (a)(15)	⊠ (b)(5)					

□ Automated Measure Calculation was not tested

3.2.9 Attestation

Attestation Forms (as applicable)	Appendix
Safety-Enhanced Design*	В
Quality Management System**	С
Privacy and Security	D

Attestation Forms (as applicable)

Appendix

*Required if any of the following were tested: (a)(1), (a)(2), (a)(6), (a)(7), (a)(8), (a)(16), (b)(3), (b)(4)

**Required for every EHR product

3.3 Appendices

Appendix A: Test Data Alterations

The following deviations from the ONC-approved Test Data were utilized during certification testing:

N/A

Appendix B: Safety-Enhanced Design Attestation

1	170.314(g)(3) Safety-enhanced design	
1.1	Identify which of the following criteria are scheduled to be tested or inherit certification.	ed for
1.1.1	170.314(a)(1) Computerized provider order entry	
1.1.2	170.314(a)(2) Drug-drug, drug-allergy interactions checks	
1.1.3	170.314(a)(6) Medication list	
1.1.4	170.314(a)(7) Medication allergy list	
1.1.5	170.314(a)(8) Clinical decision support	
1.1.6	170.314(a)(16) Electronic medication administration record (inpatient setting only)	
1.1.7	170.314(b)(3) Electronic prescribing	
1.1.8	170.314(b)(4) Clinical information reconciliation	

1.2	 Document the applied user-centered design (UCD) processes for each applicable EHR technology capability submitted for testing. Provide the name, description, and citation for all UCD processes used. If a single UCD process was used for applicable capabilities, it would only need to be
	identified once.
	 If different UCD processes were applied to specific capabilities, be sure to indicate the criterion or criteria to which each UCD process applies.
	 If a modified UCD process was used for any of the applicable capabilities, an outline and short description of the UCD process must be provided. The description must also include identifying any industry-standard UCD process upon which the modified UCD process was based.
	A single UCD process was utilized.
	A usability test of AXEIUM EHR was conducted on the referenced date and location. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT).
	During the usability test, healthcare providers, clinical and managerial staff matching the target demographic criteria served as participants and used the EHR in actual tasks. This study collected data on tasks typically conducted on an EHR relevant to the module and feature being tested.
1.3	Submit a Usability Test Report for each criterion you selected in Question 1.1.
	Attach the Usability Test Report in a separate document.
	 Identify the name of the report(s) and any other supporting documentation materials in the field below. If more than one report is submitted, specify which report applies to which criteria.
	 Reports may be supplied in any format, though they must include the necessary information for all of the certification criteria submitted for testing and conform to the content and completion requirements of the Customized Common Industry Format Template for Electronic Health Record Usability Testing per NISTIR 7742. Failure to include all required elements will constitute automatic failure of the SED Attestation.
	 The official NISTIR 7742 report template can be located at <u>http://www.nist.gov/itl/hit/upload/LowryNISTIR-</u> <u>7742Customized_CIF_Template_for_EHR_Usability_Testing_Publicationl_Version-</u>
	<u>doc.pdf</u>
	See attached '170.314(g)(3) AXEIUM EHRUT.pdf'

Appendix C: Quality Management System Attestation

1	170.314(g)(4) Quality management system
1.1	If an industry standard QMS was used during the development, testing, implementation or maintenance of the EHR technology for any of the certification criteria, specify it/them by name (e.g. ISO 9001, IEC 62304, ISO 13485, 21 CFR Part 820, etc.). If an industry standard QMS was not used, please skip to Question 1.2.
	EUP was utilized during the development process. See attached documentation '170.314(g)(4) 1.01 EUP Enterprise Unified Process'
1.2	If a modified or "home-grown" QMS was used during the development, testing, implementation or maintenance of the EHR technology for any of the certification criteria, include an outline and short description of the QMS, which could include identifying any industry-standard QMS upon which it was based and modifications to that standard. If a modified or "home-grown" QMS was not used, please skip to Question 1.3.
1.3	If no QMS was used during the development, testing, implementation or maintenance of the EHR technology for any of the certification criteria, please state that.
Append	lix D: Privacy & Security

1	Privacy & Security
1.1	AXEIUM EHR utilized AES-256 and SHA-256 for encrypting and hashing of patient information.

Test Results Summary Document History

Version	Description of Change	Date
1.0	Original	
2.0	Updated: address & logo for SLI Compliance, ACB information, Standard Successfully Tested section (a)(8)(ii)(A)(2) §170.204(b)(1) URL-Based (Infobutton)	03/13/2019 Georgia Fortun

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