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:	Soteria
Product Version:	4.1.4
Domain:	Inpatient
Test Type:	Modular EHR

1.2   Developer/Vendor Information

Developer/Vendor Name:	Infocare Healthcare Systems (Ireland) Limited
Address:	Digital Depot, Roe Lane, The Digital Hub, Thomas Street, Dublin, 8, Ireland
Website:	www.infocarehealth.com
Email:	alet.mans@infocarehealth.com
Phone:	+27 21 9139228
Developer/Vendor Contact:	Michael Kreitzer

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, CO 80033
Website:	www.slicompliance.com
Email:	Lhoppert@slicompliance.com
Phone:	303-384-5632
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	Certification Manager
ONC-ACB Authorized Representative	**Function/Title**

Lesley Hopper   12/20/2018

Signature and Date

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
☐ (a)(1)	☐ (a)(19)	☐ (d)(6)	☐ (h)(1)
☐ (a)(6)	☐ (a)(20)	☐ (d)(8)	☐ (h)(2)
☐ (a)(7)	☐ (b)(5)*	☐ (d)(9)	☐ (h)(3)
☐ (a)(17)	☐ (d)(1)	☐ (f)(1)	
☐ (a)(18)	☐ (d)(5)	☐ (f)(7)*	

*Gap certification allowed for Inpatient setting only

☒ No gap certification

2.3 Inherited Certification

The following identifies criterion or criteria certified via inherited certification

§170.314			
☐ (a)(1)	☐ (a)(16) *Inpt. only*	☐ (c)(2)	☐ (f)(2)
☐ (a)(2)	☐ (a)(17) *Inpt. only*	☐ (c)(3)	☐ (f)(3)
☐ (a)(3)	☐ (a)(18)	☒ (d)(1)	☐ (f)(4) *Inpt. only*
☒ (a)(4)	☐ (a)(19)	☒ (d)(2)	☐ (f)(5) *Optional & Amb. only*
☐ (a)(5)	☐ (a)(20)	☒ (d)(3)	
☐ (a)(6)	☐ (b)(1)	☒ (d)(4)	☐ (f)(6) *Optional & Amb. only*
☐ (a)(7)	☐ (b)(2)	☒ (d)(5)	
☐ (a)(8)	☐ (b)(3)	☒ (d)(6)	☐ (f)(7) *Amb. only*
☒ (a)(9)	☐ (b)(4)	☒ (d)(7)	☒ (g)(1)
☐ (a)(10)	☐ (b)(5)	☒ (d)(8)	☐ (g)(2)
☒ (a)(11)	☐ (b)(6) *Inpt. Only*	☐ (d)(9) *Optional*	☐ (g)(3)
☐ (a)(12)	☐ (b)(7)	☐ (e)(1)	☒ (g)(4)
☐ (a)(13)	☐ (b)(8)	☐ (e)(2) *Amb. only*	☐ (h)(1)
☒ (a)(14)	☐ (b)(9)	☐ (e)(3) *Amb. only*	☐ (h)(2)
☐ (a)(15)	☐ (c)(1)	☐ (f)(1)	☐ (h)(3)

☐ No inherited certification

Part 3: NVLAP-Accredited Testing Laboratory Information

Report Number: N/A

Test Date(s): N/A

3.1   NVLAP-Accredited Testing Laboratory Information

ATL Name:	SLI Compliance, a Division of Gaming Laboratories International, LLC
Accreditation Number:	200733-0
Address:	4720 Independence St. Wheat Ridge, CO 80033
Website:	http://www.slicompliance.com/
Email:	info@slicompliance.com
Phone:	303-422-1566
ATL Contact:	Dustin George

For more information on scope of accreditation, please reference http://ts.nist.gov/standards/scopes/2007330.htm

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

Dustin George	Health IT Test Lab Manager
ATL Authorized Representative	**Function/Title**

_____ 12/19/2018
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
Quippe	ONC 314a9	Enable a user to electronically record, change, access, and search electronic notes

Additional Software	Applicable Criteria	Functionality provided by Additional Software
Unix NTPD	ONC 314d2	Synchronize EHR server time with NIST time servers.

☐ No additional software required

3.2.2 Test Tools

Test Tool	Version
☐ Cypress	
☐ ePrescribing Validation Tool	
☐ HL7 CDA Cancer Registry Reporting Validation Tool	
☐ HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	
☐ HL7 v2 Immunization Information System (IIS) Reporting Validation Tool	
☐ HL7 v2 Laboratory Results Interface (LRI) Validation Tool	
☐ HL7 v2 Syndromic Surveillance Reporting Validation Tool	
☐ Transport Testing Tool	
☐ Direct Certificate Discovery Tool	
☐ Edge Testing Tool	

☒ No test tools required

3.2.3 Test Data

☐ Alteration (customization) to the test data was necessary and is described in Appendix [*Appendix A*]

☒ 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

Criterion #	Standard Successfully Tested	
(a)(8)(ii)(A)(2)	☐ §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
(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 ● [*Enter encryption and hashing algorithms*]	
(e)(1)(ii)(A)(2)	☐ §170.210(g) Network Time Protocol Version 3 (RFC 1305)	☐ §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(e)(3)(ii)	☐ Annex A of the FIPS Publication 140-2 ● [*Enter encryption and hashing algorithms*]	

Criterion #	Standard Successfully Tested	
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 Version	Applicable Criteria

☒ 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

Criteria #	Version TP**	Version TD***	Criteria #	Version TP	Version TD
☐ (a)(1)			☐ (c)(3)		
☐ (a)(2)			☐ (d)(1)		
☐ (a)(3)			☐ (d)(2)		
☐ (a)(4)			☐ (d)(3)		
☐ (a)(5)			☐ (d)(4)		
☐ (a)(6)			☐ (d)(5)		
☐ (a)(7)			☐ (d)(6)		
☐ (a)(8)			☐ (d)(7)		
☐ (a)(9)			☐ (d)(8)		
☐ (a)(10)			☐ (d)(9) *Optional*		
☐ (a)(11)			☐ (e)(1)		
☐ (a)(12)			☐ (e)(2) *Amb. only*		
☐ (a)(13)			☐ (e)(3) *Amb. only*		
☐ (a)(14)			☐ (f)(1)		
☐ (a)(15)			☐ (f)(2)		
☐ (a)(16) *Inpt. Only*			☐ (f)(3)		
☐ (a)(17) *Inpt. Only*			☐ (f)(4) *Inpt. only*		
☐ (a)(18)			☐ (f)(5) *Optional & Amb. only*		
☐ (a)(19)					
☐ (a)(20)			☐ (f)(6) *Optional & Amb. only*		
☐ (b)(1)					
☐ (b)(2)			☐ (f)(7) *Amb. only*		
☐ (b)(3)			☐ (g)(1)		
☐ (b)(4)			☐ (g)(2)		
☐ (b)(5)			☐ (g)(3)		
☐ (b)(6) *Inpt. Only*			☐ (g)(4)		
☐ (b)(7)			☐ (h)(1)		
☐ (b)(8)			☐ (h)(2)		
☐ (b)(9)			☐ (h)(3)		
☐ (c)(1)					
☐ (c)(2)					

Criteria #	Version		Criteria #	Version	
	TP**	TD***		TP	TD

*For a list of the 2014 Edition Certification Criteria, please reference http://www.healthit.gov/certification (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 the CMS eCQM Library (Navigation: June 2014 and April 2014 Updates)

Ambulatory CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
☐ 2		☐ 90		☐ 136		☐ 155	
☐ 22		☐ 117		☐ 137		☐ 156	
☐ 50		☐ 122		☐ 138		☐ 157	
☐ 52		☐ 123		☐ 139		☐ 158	
☐ 56		☐ 124		☐ 140		☐ 159	
☐ 61		☐ 125		☐ 141		☐ 160	
☐ 62		☐ 126		☐ 142		☐ 161	
☐ 64		☐ 127		☐ 143		☐ 163	
☐ 65		☐ 128		☐ 144		☐ 164	
☐ 66		☐ 129		☐ 145		☐ 165	
☐ 68		☐ 130		☐ 146		☐ 166	
☐ 69		☐ 131		☐ 147		☐ 167	
☐ 74		☐ 132		☐ 148		☐ 169	
☐ 75		☐ 133		☐ 149		☐ 177	
☐ 77		☐ 134		☐ 153		☐ 179	
☐ 82		☐ 135		☐ 154		☐ 182	

Inpatient 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			
☐ 60		☐ 105		☐ 171			

3.2.8 Automated Numerator Recording and Measure Calculation

3.2.8.1 Automated Numerator Recording

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

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*	
☒ Quality Management System**	B
☐ Privacy and Security	

*Required if any of the following were tested: (a)(1), (a)(2), (a)(6), (a)(7), (a)(8), (a)(16), (a)(18), (a)(19), (a)(20), (b)(3), (b)(4), (b)(9).

**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:

- 170.314(g)(2) eNotes measure – System does not allow unauthorized providers to enter clinical notes

Appendix B: 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.
	n/a
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.
	Infocare has a home-grown QMS which forms part of Infocare's SDLC. Infocare's SDLC and its underlying processes are aligned to ITIL. The ITIL service lifecycle is based on ITIL's core concept of "service management" and the related concepts "service" and "value". Quality Management is addressed in all 5 stages of ITIL's service lifecycle. The Quality Assurance processes are also following the ISO/IEC/IEEE 29119 standard. Alignment to other standards: Auditing. Aligned to ISO 27789 Health informatics audit trail for electronic health records Minimal level of security as outlined in the Common Criteria [ISO15408-2] Date and time format. Format according to the ISO 8601 standard [ISO8601] Lists of Countries. ISO 3166 is used as a starter set for reference data List of Languages. ISO 639 is used as a starter set for reference data
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.
	n/a

Appendix C: Privacy & Security

1	Privacy & Security
1.1	

Test Results Summary Document History

Version	Description of Change	Date
1.0	Original	
2.0	Update to include 2014 Release 2 Certification Criterion and 2014 Clinical Quality Measures for EP and EH	

END OF DOCUMENT