



ADL Data Systems Optimum Order Entry and Financials

DEA EPCS Certification Test Report Addendum 2016 to Report #150107-iBetaCTR-v1.0

Prepared for
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Trace to Standards

21 CFR Parts 1300, 1304, 1306, 1311

Test Results in this report apply to the EPCS signing application system configuration tested. Testing of EPCS applications that have been modified may or may not produce the same test results. This report shall not be reproduced, except in full.

iBeta Quality Assurance is approved for DEA-EPCS Application Testing

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for a period of 2 years from that date however as this is an addendum without regression of major functionality, the certification expiration is unchanged from the Addendum 2015 date.

Date of expiration:

10 - 07- 2017

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Version History

Ver #	Description of Change	Author	Approved by	Date
v1.0	Released Certification Report	<i>Gail Audette</i>	<i>Dr. Kevin Wilson</i>	<i>7 January 2015</i>
Addendum 2015	Addendum for re-certification	<i>Gail Audette</i>	<i>Dr. Kevin Wilson</i>	<i>7 October 2105</i>
Addendum 2016	Addendum for re-certification to add MiFARE card and NG-OTP eToken	<i>Gail Audette</i>	<i>Dr. Kevin Wilson</i>	<i>1 April 2016</i>

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1 Executive Summary

This 2016 Addendum to the Certification Report 150107-iBetaCTR-v1.0 and Addendum 2015 contains the results, conclusions and recommendations of the iBeta Quality Assurance assessment for re-certification of the DEA EPCS compliant Optimum Financials Version EPCS1.03 and Order Entry Version EPCS 1.03 from ADL Data Systems. Re-Certification functional testing was performed from 8 February 2016 through 30 March 2016 and validated the applicable with modifications from the certified configuration continue to meet the requirements of 21 CFR Part 1311 for an application used for the Electronic Prescription of Controlled Substances System (EPCS).

iBeta re-certifies that Optimum Financials Version EPCS 1.03 and Order Entry Version EPCS 1.03 meet the requirements of 21 CFR Part 1311 as applicable and other applicable requirements contained in Parts 1300, 1304, and 1306. This system meets the requirements to be used for EPCS for a prescription signing system.

This report addendum is provided to ADL Data Systems for distribution and is available for distribution by iBeta at the written request of ADL Data Systems. The report will be delivered to the DEA in accordance with the iBeta approval letter and will be maintained within iBeta SharePoint document system for 2 years after the date printed on the cover of this report.

1.1 System Identification

The ADL Data System application re-certified and documented within this Final Report Addendum is for the Order Entry RO: 2016-03-01 EPCS 1.03 and Optimum Financials Version OFU 35.13 EPCS 1.03 exclusively.

1.2 Disclosure

This addendum is a change to the ADL Data Systems Optimum Order Entry and Financials DEA EPCS Certification Test Report #150107-iBetaCTR-v1.0 dated 7 January 2015 and an addition to the Addendum 2015 dated 7 October 2015. This addendum documents the modifications to the previously certified applications, the testing of those modifications, and the re-certification versions. This addendum modifies but does not replace the certification as documented in Report #150107-iBetaCTR-v1.0 or the 2015 Addendum and the versions certified previously will expire two years from the date of that report.

This addendum adds the certification of the modifications to the original certification and does not alter the intent or purpose of the original certification report. Only the sections that have been modified from the original certification report are documented herein.

iBeta tested the updated application as described in the System Identification section of this report. iBeta believes this information is sufficient to allow end point users to verify that the application they are implementing is the same application that iBeta has certified. The vendor, ADL Data Systems, is aware that the certification expires two years from the date listed on this report, or if the application is modified, whichever comes first [21 CFR 1311.300(e)(2)]. It is the end point user's responsibility to verify that they are using a certified version.

2 Introduction

This report is generated to document iBeta Quality Assurance re- assessment and re-testing of an EPCS Prescriber application as per 21 CFR 1311.300(e).

Testing was conducted at iBeta Quality Assurance facility in Aurora, Colorado via WebEx for access to the application for testing. Screen shots were captured and uploaded into the test cases as test steps were validated.

Re-Certification testing was performed in compliance with the requirements of 21 CFR Parts 1300, 1304, 1306 and 1311. The test record included all regression testing.

2.1 Internal Documentation

The documents identified below are in addition to those used in certification testing.

Table 1 Internal Documents

Version #	Title	Abbreviation	Date
Rev 01	Agreement for EPCS Re-Certification Testing Services	Contract	11/13/15
iBeta	Project Documents		
Rev 01	DEA-EPCS Requirement for ADL Prescriber Re-Certification		3/30/16

Version #	Title	Abbreviation	Date
Rev 01	DEA EPCS ADL Prescriber Regression Test Cases		3/30/16

2.2 External Documentation

No addition external documents were required for re-certification.

2.3 Technical Documents

Additional Technical Documents submitted for this re-certification test effort are listed in Section 3 System Identification.

2.4 Test Report Addendum Contents

The contents of this Re-Certification Test Report Addendum include:

- Section 1: The Introduction - identifies the scope of certification testing.
- Section 2: The Certification Test Background identifies the process for certification testing.
- Section 3: The System Identification identifies the system configuration including hardware, software and the technical documentation.
- Section 4: The System Overview identifies the overall design and functionality of EPCS system.
- Section 5: The Certification Review and Test Results are the methods and results of the testing effort.
- Section 6: The certification statement of the EPCS system.

Test Operations, Findings and Data Analysis are in the appendices.

- Appendix A: Security Assessment Results for DEA-EPCS Conformance
- Appendix B: Discrepancy Report
- Appendix C: Test Cases (bound separately)
- Appendix D: Configuration Management (Git) Application Files (bound separately)

3 Certification Test Background

The prescriber application submitted for re-certification has been certified for DEA EPCS previously so only a regression suite of tests were performed based on the modification to the certified version.

3.1 Terms and Definitions

The Terms and Definitions identified below are used in this test report.

Table 2 Terms and Definitions

Term	Abbreviation	Definition
Authentication	Auth	The process whereby a claimant provides evidence to a system that the claimant is in fact the person claimed and not an imposter.
Conformance Test Suite	CTS	A test program utilized to provide data such as biometric data to the IUT and automatically obtain results (such as a similarity score) in response to a particular challenge.
Drug Enforcement Agency	DEA	United States Department of Justice Drug Enforcement Agency
Electronic Prescription of Controlled Substances	EPCS	Program allowing physicians and their agents to electronically transmit prescriptions to a dispensary such as a pharmacy.
Factor		In authentication, one of the pieces of evidence that is used to support the identity claim of the claimant.
Filling Application	FA	An application used to fill an electronic prescription or an application that acts as an intermediary between the signing application and the location where the electronic prescription is filled or dispensed.
Independent Test Lab	ITL	Lab accredited by NVLAP
National Voluntary Laboratory	NVLAP	Part of NIST that provides third-party accreditation

Term	Abbreviation	Definition
Accreditation Program		to testing and calibration laboratories.
Not Applicable	NA	A regulation that has been assessed as not applicable to the prescriber application being submitted for DEA EPCS Certification.
Not Testable	NT	A regulation or sub-set of the regulations that are not testable.
Pharmacy Application		A Filling Application specifically performing functions for a pharmacy.
System under test	SUT	The computer system of hardware and software on which the implementation under test operates
Signing Application	SA	The application used by the practitioner to apply a digital signature to the electronic prescription.
Tested Elsewhere	TE	A regulation that has been assessed to apply to the prescriber application but is being tested within another regulation.
Vendor		System/application manufacturer

3.2 DEA-EPCS Re-Certification

Under 21 CFR 1300, 1304, 1306 and 1311, the DEA Office of Diversion Control specifies and regulates the operation of Electronic Prescription of Controlled Substances (EPCS). The regulations require an independent third-party to review and test the application and validate that it meets the requirements in 21 CFR 1311 and elsewhere as referenced. In addition, application providers must obtain a third-party audit every two years after the initial audit or whenever the functionality is modified, whichever occurs first where in this re-certification effort, the functionality being modified prior to the two year expiration of the original certification test effort is driving this test effort.

3.2.1 Definition of Test Cases

The test criteria were defined as the regulations that applied to the certification candidate based on the modification to the previously certified versions. For this re-certification test effort, the following modifications impacting the two-factor authentication functionality only were reviewed:

- a. MiFARE Ultralight C card update.
- b. Addition of the Aladdin NF-OTP e-token.

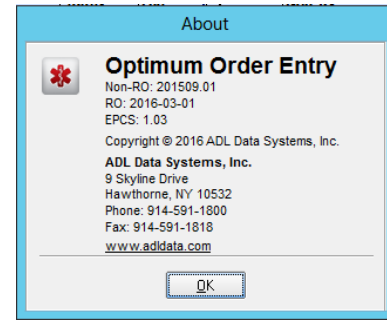
One functional test case and one static test case were identified as the regression test suite and executed. The as-run test cases are provided as Appendix C to this report and summarized as follows:

- Partial Regression of Test Case 5 – Two-Factor Authentication
- Partial Regression of Test Case 10 – Source Code Review

The security aspects of the application were assessed using 21 CFR 1311 requirements as guidelines along with the DEA Clarification dated 19-October-2011 to include “processing integrity” utilizing NIST SP800-53A as a guideline.

3.2.2 Test Environment Setup

The test environment was controlled and maintained by ADL Data Systems and accessed by iBeta via WebEx only. As a result, iBeta conducted a review of the application changes from the start of testing on 8 February 2016 through the issue date of this report to verify that the application under test is the application being recommended for certification. iBeta captured screen shots of the application under test to record the configuration tested.



3.2.3 Test Execution

Functional test execution was conducted from February 8, 2016 through March 30, 2016. The summary results are listed in Appendix A.

3.2.3.1 Deviations and Exclusions

Any deviations from or exclusions to the test method are documented, technically justified, authorized and accepted by the customer and are documented as such in Appendix A.

There were no deviations or omissions from the standards.

4 System Identification

The System Identification stipulates the ADL Data Systems Optimum Financials Version EPCS 1.03 and Order Entry Version EPCS 1.03 submitted for certification and the hardware, software and the documentation used in testing.

4.1 Submitted System Identification

Table 3 System Name and Version

System Name	Version
Optimum Financials	EPCS 1.03
Order Entry	EPCS 1.03

4.2 System Test Environment

The test environment was the ADL Data Systems Quality Assurance test environment. The documentation provided throughout the test effort is delineated below.

Table 4 ADL Data Systems Documentation

File Name	Document Date	Date Received
Key Registration Steps.pdf		9/23/14
Aarons DEA Certification Document_rev1.pdf	9/1/14	9/23/14
Professionals Module Prescriber Update_rev1.pdf		9/23/14
Time_Synchronization_External_Source_rev1.pdf		9/23/14
Emergency Medication Supply_rev1.pdf		9/23/14
Aarons DEA Certification Document_highlight(1).docx		10/1/14
Emergency Medication Supply.docx		10/1/14
Setting_system_to_fips.doc		10/1/14
dea_test_steps.doc		11/10/14
FIPS 140-2.pdf		11/10/14
adding_a_professional_REV1.pdf		11/10/14
Key Registration Steps_REV1.pdf		11/10/14

File Name	Document Date	Date Received
EPCS Policy and Procedure Guide.pdf	12/11/14	12/11/14
RFP Responses KS ADL Nov2 2012 1 2_Physical Security pg3.pdf		12/17/14
Contract ADL 6 2013_Backups and Restoreds.pdf - Appendix A Service Schedule No. [1]		12/17/14
EPCS Policy and Procedure Guide.pdf	8/31/15	8/31/05

Table 5 Other Software, Hardware and Materials

Material	Material Description	Use in the Biometrics System
Other		
Multiple desktop and laptop PCs	A variety of PCs running Microsoft operating systems	Supplied by iBeta: Preparation, management and recording of test plans, test cases, reviews and results
Repository servers	Separate servers for storage of test documents and source code, running industry standards operating systems, security and back up utilities	Supplied by iBeta: Documents are maintained on a secure network server. Source code is maintained on a separate data disk on a restricted server
Microsoft Office 2010	Excel and Word software and document templates	Supplied by iBeta: The software used to create and record test plans, test cases, reviews and results
SharePoint 2010	Test documentation repository	Supplied by iBeta: Vendor document and test documentation repository and configuration management tool
Other standard business application software	Internet browsers, PDF viewers email	Supplied by iBeta: Industry standard tools to support testing, business and project implementation

4.3 Order Entry Component Capabilities

The Order Entry component provides the physician with the function to create, update and sign electronic Physician Orders. This component is expanded to allow for electronic prescribing of controlled substances in accordance with the 21 Part 1311 regulations. The current released component provided managed patient status, real-time order entry, electronically created and signed orders, and ease of use through order templates.

4.4 Financials Component Capabilities

The Financials component controls the access control for the prescriber. By requiring roles based access and two-factor authentication, the component meets the regulations for establishing the access control required for electronic prescribing of controlled substances.

5 Re-Certification Review and Test Results

The results and evaluations of the assessment tests are identified below. Detailed data regarding the Acceptance/Rejection criteria, reviews and tests are found in the appendices.

- Appendix A identifies all certification test results for Security Assessment Testing
- Appendix B identifies the Discrepancies reported during review and testing
- Appendix C provides the Test Cases as executed
- Appendix D provides the full list of the certification candidate software files as exported by the Git Configuration Management tool

5.1 Limitations

The results and conclusions of this report are limited to the specific certification candidate applications and versions described below.

It is the responsibility of the vendor to provide the laboratory with systems and devices which are representative of those systems and devices produced for the consumer.

These results represent usage of falsification testing methodology. Testing can only demonstrate non-conformity, i.e., if errors are found, non-conformance of the System-Under-Test (SUT) shall be proven, but the absence of errors does not necessarily imply the converse. These results are intended to provide a reasonable level of confidence and practical assurance that the SUT conforms to the standard. Use of these results will not guarantee conformity of an implementation to the standard; that normally would require exhaustive testing, which is impractical for both technical and economic reasons.

5.2 DEA EPCS Review

5.2.1 Optimum Financials Version EPCS 1.03 Component Results

The Access Control regulations were not impacted by the modifications; however, during functional testing of Test Case 5 (to test the Two –Factor Authentication), iBeta did witness the execution of a new prescriber being added for each of the tokens. There were neither deviations from the standard test method nor any test setup that varied from the standard protocol. All of the functionality for EPCS contained within the Optimum Financials component remains validated.

5.2.1.1 Exceptions

For the Access Control functions provided by the Optimum Financials component, Institutional Practitioners (per 1306.05(g) & (h), 1311.110, 1311.120(b)(1)(ii), and 1311.130) were not supported and are excluded from this certification.

The data supporting this review are found in Appendix A.

5.2.2 Order Entry Version EPCS 1.03 Component Results

The Order Entry component regulations were addressed and tested within 2 I regression test cases. All test cases were successfully executed. There were neither deviations from the standard test method nor any test setup that varied from the standard protocol. All of the functionality for EPCS contained within the Order Entry component remains validated and/or verified.

5.2.2.1 Exceptions

For the Order Entry functions within this component, three functions were not supported and are excluded from this certification:

- Prescribing for detoxification or maintenance treatments per 1306.05(b)
- Biometrics as one of the two-factor authentication per 1311.116
- Prescribing of more than one controlled substance at one time for a particular patient per 1311.120(b)(13)

The data supporting this review are found in Appendix A.

6 Opinions & Recommendations

6.1 Recommendations

iBeta Quality Assurance has completed the testing of ADL Data Systems Optimum Financials Version EPCS 1.03 and Order Entry Version EPCS 1.03. In our opinion the acceptance requirements of 21 CFR 1311 have been met.

Table 7 contains a summary of the 21 CFR 1311 requirements that were found to be in compliance with the regulation.

Table 6 Summary of Requirements

Requirement	Description	Approved
1311.05	Standards for technologies for electronic transmission of orders.	<input checked="" type="checkbox"/>
1311.100	General.	<input checked="" type="checkbox"/>
1311.102	Practitioner responsibilities	<input checked="" type="checkbox"/>
1311.105	Requirements for obtaining an authentication credential—Individual practitioners.	<input checked="" type="checkbox"/>
1311.110	Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.	<input checked="" type="checkbox"/>
1311.115	Additional requirements for two-factor authentication.	<input checked="" type="checkbox"/>
1311.116	Additional requirements for biometrics – not applicable.	<input checked="" type="checkbox"/>
1311.120	Electronic prescription application requirements.	<input checked="" type="checkbox"/>
1311.125	Requirements for establishing logical access control—Individual practitioner.	<input checked="" type="checkbox"/>
1311.130	Requirements for establishing logical access control—Institutional practitioner – not applicable.	<input checked="" type="checkbox"/>
1311.135	Requirements for creating a controlled substance prescription.	<input checked="" type="checkbox"/>
1311.140	Requirements for signing a controlled substance prescription.	<input checked="" type="checkbox"/>
1311.145	Digitally signing the prescription with the individual practitioner's private key	<input checked="" type="checkbox"/>
1311.150	Additional requirements for internal application audits.	<input checked="" type="checkbox"/>
1311.170	Transmission requirements.	<input checked="" type="checkbox"/>
1311.200	Pharmacy responsibilities – not applicable.	<input checked="" type="checkbox"/>
1311.205	Pharmacy application requirements – not applicable.	<input checked="" type="checkbox"/>
1311.210	Archiving the initial record.	<input checked="" type="checkbox"/>
1311.215	Internal audit trail.	<input checked="" type="checkbox"/>
1311.300	Application provider requirements—Third-party audits or certifications.	<input checked="" type="checkbox"/>
1311.305	Recordkeeping.	<input checked="" type="checkbox"/>
1311	Clarification 19 October 2011	<input checked="" type="checkbox"/>

iBeta Quality Assurance certifies ADL Data Systems Optimum Financials Version EPCS 1.03 and Order Entry Version EPCS 1.03 as a prescriber system for EPCS.

6.1.1 Limitations

As described in section 5.1 Limitations, iBeta has tested what it believes to be a representative sample of the commercially available system and used the appropriate test methods to test conformance to the standards. Device or system behavior which falls outside of the scope of testing is not certified.

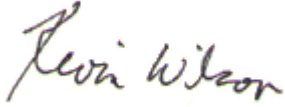
6.1.2 Exceptions

The ADL Data System application does not support the following functionality and was neither tested nor certified against the corresponding DEA EPCS regulations:

- Detoxification or maintenance treatments per 1306.05
- Institutional Practitioners per 1306.05, 1311.110, 1311.120 and 1311.130
- Biometrics as one of the two-factor authenticators per 1311.116
- Prescribing more than one controlled substance at one time for a single patient per 1311.120

6.2 Opinions

Based upon the testing conducted and the exceptions documented herein, iBeta Quality Assurance certifies ADL Data Systems Optimum Financials Version EPCS 1.03 and Order Entry Version EPCS 1.03 as a prescriber system for EPCS.

A handwritten signature in cursive script that reads "Kevin Wilson".

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7 APPENDICES: TEST OPERATION, FINDINGS & DATA ANALYSIS

Appendix A: Security Assessment Results for DEA-EPCS Conformance

The DEA-EPCS assessment matrix for the Signing Agent (Physician) based upon the Department of Justice Drug Enforcement Administration 21 CFR Parts 1300, 1304, 1306, and 1311 [Docket No. DEA-218] Electronic Prescriptions for Controlled Substances remains unchanged from the Certification Report 150107-iBetaCTR-v1.0.

Result	Result Definition	Total
Pass	Regulation has been assessed as being met during the Certification.	170
Fail	Regulation has not been assessed as being met by the design, documentation, or demonstration of the prescriber application during Certification.	0
NT	Not Testable: This regulation or sub-set of the regulations is not testable.	27
NA	Not Application: This regulation has been assessed as not applicable to the prescriber application being submitted for DEA EPCS Certification.	22
TE	Test Elsewhere: This regulation has been assessed to apply to the prescriber application but is being tested within another regulation.	64
Total Regulations for Certification		283

Appendix B: Discrepancy Report

Additional discrepancies were reported and tracked to closure during the re-certification test effort within the Test Case 10 – Source Code Review. Those discrepancies are reported in Appendix C.