BlockID V1.5.21

DEA EPCS Biometric Subsystem Certification Test Report

Prepared for:

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Trace to Standards
21 CFR Part 1311.116

Test Results in this report apply to the biometrics system configuration tested. Testing of biometric systems 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 DEA approved for Biometric System Testing.

Date of publication:
December 17, 2021

This report is made public as of the above date.
It will be maintained at ***http://www.ibeta.com*** *for a period of 2 years from that date.*

Date of expiration:
December 17, 2023

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Version History

Ver #	Description of Change	Author	Approved by	Date
V1.0	Draft Certification Report for 1Kosmos	Ryan Borgstrom	Gail Audette	17-December 2021
V2.0	Final Report based on OneKosmos review	Gail Audette	Ryan Borgstrom	11-January 2022

TABLE OF CONTENTS

1 Executive Summary

This report contains the results and conclusions of the iBeta Quality Assurance assessment that resulted in the certification of the biometric subsystem consisting of BlockID v1.5.21 with the SaaS cloud-based solution (version Pl_co_1.05) from 1Kosmos. The biometric subsystem was validated and certified against the applicable requirements of 21 CFR Part 1311.116 for its inclusion as a built-in subsystem in an Electronic Prescription of Controlled Substance (EPCS) Application.

The 1Kosmos biometric system is a facial recognition based technology that acquires images of the face, converts the images using a 1Kosmos proprietary algorithm, and matches those images to their reference (enrollment) templates.

The 1Kosmos BlockID biometric subsystem was validated to operate at a False Match Rate (FMR) of 0.001 or lower across five iOS and five Android smart phone devices. The operating point corresponding with the False Match Rate described in 1311.116(b) was tested so that there was at least 95% confidence that the False Match Rate was equal to or less than the required value. To validate the False Match Rate requirement of 0.001 or lower as cited in 1311.116(b), iBeta found that the biometric subsystem meets the requirement. The hardcoded threshold, that iBeta did not have access to was tested on all devices accessing the SaaS back-end solution.

The application utilized for testing is consistent on all platforms; however, iBeta only tested the BlockID biometric solution on 5 iOS devices (iPhone XR, iPhone XS, iPhone 11, iPhone 11 Pro, iPhone 12 Pro Max) and 5 Android devices (Google Pixel 3a, Google Pixel 4, Samsung Galaxy Note 10, Samsung Galaxy S10, and Samsung Galaxy S10+).

The 1Kosmos biometric subsystem was tested to the DEA EPCS regulations with 21 CFR Part 1311.116. All other EPCS requirements are out of scope of this report.

This report is publicly available and Attachment 1 is available upon request from 1Kosmos, Inc. This report will be maintained on the iBeta website during the period of certification from the issuance of this report (17 December 2021) through certification expiration date (17 December 2023).

1.1 *Biometric Subsystem Identification*

The BlockID acquisition components and the SaaS cloud-based solution for matching are described in Section 4.1 Submitted Biometric Subsystem Identification and 4.2 Biometric Subsystem Test Environment. The smart phone-based applications used for testing were downloaded from Apple's App Store for iOS testing and the Play Store for Android testing and the back-end solution was accessed via those applications.

1.2 *Disclosure*

This report consists of the publicly available assessment and test results made between the independent test organization, iBeta Quality Assurance LLC and the vendor. This report is made public in accordance with DEA requirements and is located at www.ibeta.com.

Additional results are proprietary and not made public but disclosed to the vendor:

- Attachment 1: Detailed Technology Assessment Results

Information and data not disclosed outside of the testing lab include:

- Technology Test data used to determine the FMR;
- Test Design Procedures; and
- Test Case templates and as-run Test Cases.

2 Introduction

This report was generated to document iBeta Quality Assurance's assessment and testing of a biometric subsystem for the purpose of that subsystems' inclusion in an Electronic Prescription of Controlled Substances (EPCS) system. This report addresses the testing of the 1Kosmos applications to the 21 CFR 1311.116 regulations. The results were for the 1Kosmos BlockID Facial Biometric System with the associated BlockID cloud-based server. Subjects first performed 30 zero-effort impostor attempts (15 attempts across five iOS devices, and 15 attempts across five Android devices), and then performing an enrollment (1 on an iOS device, 1 on an Android device), followed by genuine verification transactions (5 against the iOS device's enrollment, 5 against the Android device's enrollment).

The purpose of this document is to provide an overview of the certification testing and findings. The complete list of the systems names, major subsystems, version numbers and any interfacing devices is contained in Section 4 - Biometric System Identification. Additional details of the design, structure, and processing capabilities are identified in the Section 5 - Biometric System Overview.

Testing was conducted at the iBeta Quality Assurance facility in Aurora, Colorado.

Certification testing was performed in compliance with the requirements of 21 CFR 1311.116. All test executions and reviews included the record of requirements that were satisfactorily and unsatisfactorily completed. No deficiencies were noted during the test effort.

The New England Independent Review Board (NEIRB) reviewed the iBeta DEA-EPCS Biometric Test Protocol application and granted unconditional approval on 17 August 2020 (approval: #120160885) for the following:

- Test Protocol Version 1.0 dated 19 August 2016
- Biometrics Security Procedures (Version 4.0) dated 13 September 2019
- DEA-EPCS Biometric Subsystem Assessment Procedure (Version 4.0) dated 21 May 2013
- Biometrics Testing Disclaimer (Version 1.0)
- Brochure - 'Biometrics Testing Lab'
- Informed Consent Form (NEIRB Version 1.0)

The certification test effort was conducted in full compliance with the IRB approved study protocol.

The requirement of 21 CFR 1311.116(b) is that the biometric subsystem operate at a False Match Rate (FMR) of 0.001 or lower. Technology testing for the FMR requirement was performed using ISO/IEC 19795-1 and ISO/IEC 19795-2 as guidance documents in the generation and execution of test cases.

iBeta Quality Assurance, a limited liability company, is located in Aurora, Colorado. The company is a full service software testing laboratory providing Quality Assurance and Software Testing for the business and interactive entertainment communities.

2.1 *Internal Documentation*

The documents identified below are iBeta internal documents used in certification testing.

Table 2-1 Internal Document

Version #	Title	Abbreviation	Date	Author (Org.)
01	DEA EPCS Biometric Subsystem Certification – 1Kosmos v1	Contract	04/27/2021	iBeta Quality Assurance
01	iBeta Biometric NDA – 1Kosmos	NDA	04/27/2021	iBeta Quality Assurance
iBeta Procedures				
2.0	Biometric Deliverable Receipt Procedure		2/21/20	iBeta Quality Assurance

Version #	Title	Abbreviation	Date	Author (Org.)
4.0	Biometric Security Procedure		8/16/13	iBeta Quality Assurance
1.0	Biometrics Configuration Management Procedure		6/9/11	iBeta Quality Assurance
1.0	DEA-EPCS Biometric Assessment Procedure		5/21/13	iBeta Quality Assurance
1.0	Biometric Training and Training Records Procedure		6/1/11	iBeta Quality Assurance
iBeta Project Documents				
1.0	DEA-EPCS-Biometric-Assessment-1Kosmos		10/04/2021	iBeta Quality Assurance
1.0	Pre-Certification Letter		10/04/2021	iBeta Quality Assurance
1.0	DEA-EPCS-Cert-1Kosmos		12/13/2021	iBeta Quality Assurance

2.2 *External Documentation*

The documents identified below are external resources used to in certification testing.

Table 2-2 External Documents

Version #	Title	Abbreviation	Date	Author (Org.)
2017	ISO/IEC 17025: 2017 – General requirements for the competence of testing and calibration laboratories	ISO/IEC 17025: 2017	2017-11-29	ISO/IEC
2010	ISO/IEC 17043:2010 – International Standard: Conformity assessment – General requirements for proficiency testing	ISO/IEC 17043:2010	2010-02-01	ISO/IEC
2021	ISO/IEC 19795-1:2021 Information technology — Biometric performance testing and reporting — Part 1: Principles and framework	ISO 19795-1 Or 19795-1	May 01, 2021	ANSI ISO
2007	ISO/IEC 19795-2:2007 Information technology — Biometric performance testing and reporting — Part 2: Testing methodologies for technology and scenario evaluation	ISO 19795-2 Or 19795-2	Feb 01, 2007 (ANSI adoption)	ANSI ISO
31 Mar 2010	21 CFR Part 1311.116 Additional Requirements for Biometrics	Regulations	31 Mar 2010	Drug Enforcement Administration (DEA) Department of Justice, Office of Diversion Control
31 Mar 2010	21 CFR Parts 1300, 1304, 1306, and 1311 Electronic Prescriptions of Controlled Substances	Interim Final Rule	Effective Date 1 June 2010	Drug Enforcement Administration (DEA) Department of Justice, Office of Diversion Control
19 Oct, 2011	Docket No. DEA-360 Clarification and Notification		19 Oct, 2011	DEA Office of Diversion Control

2.3 *Test Report Contents*

The contents of this Test Report include:

- Section 1: The Executive Summary identifies a brief summary of results and conclusions of the certification testing.
- Section 2: The Introduction identifies the scope of certification testing.
- Section 3: The Certification Test Background identifies the process for certification testing.
- Section 4: The Biometric Subsystem Identification identifies the system configuration including hardware, software and the technical documentation.
- Section 5: The Biometric Subsystem Overview identifies the subsystem functionality capabilities.
- Section 6: The Certification Review and Test Results are the methods and results of the testing effort.
- Section 7: The Opinions and Recommendations section identifies the certification and limitations of that certification based upon the results of Section 6.

Detailed Results and Data Analysis are in Attachment 1: Detailed Technology Assessment Results.

3 Certification Test Background

As a background for this biometric subsystem 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) applications. The regulations require 2-factor authentication of individuals to a system that electronically prescribes controlled substances. The regulations allow for two of three factors to be used for authentication. One of those factors may include a biometric from the individual claiming an identity.

Certification testing of the 1Kosmos BlockID Biometric Subsystem included Security Assessment and Operating Point to provide 0.001 false match rate or better.

3.1 *Terms and Definitions*

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

Table 3-1 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.
Biometric characteristic		A specific type of physical attribute associated with an individual that may be used to establish identity. Examples are fingerprint, iris, facial, hand geometry, vein print, vein pattern, gait and signature.
Biometric Sample	biometric	Information obtained from a biometric sensor, either directly or after further processing
Biometric Subsystem		As viewed from the perspective of an overall prescription signing system or application, the biometric subsystem is that portion of the system used to provide the biometric authentication when a biometric is used as one of the two factors of authentication.
Biometrics Identification	BID	The anonymous 6 digit subject identification of biological characteristics
Built-In		iBeta's DEA approved process describes a 'built-in' biometric subsystem as a subsystem that is primarily enclosed by the overall EPCS system. It therefore relies on the enclosing system to satisfy most or all of the DEA regulations for EPCS.
Claimant		Person claiming to have an identity for which the biometric subsystem will validate the claim
Commercial Off-the-Shelf	COTS	Commercial Off-The-Shelf; An item that is both commercial and sold in substantial quantities in the commercial marketplace
Confidence Interval	CI	Confidence intervals consist of a range of values (interval) that act as good estimates of the unknown population parameter. In the context of this report and ISO 19795, the confidence interval is purely statistical in estimation.
Conformance Test Software	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	The United States Department of Justice Drug Enforcement Agency. The Office of Diversion Control specifically handles the regulations discussed in this report.

Term	Abbreviation	Definition
Detection Error Trade-off	DET	A graphical plot of error rates for binary classification systems, plotting false reject rate vs. false accept rate
Distortion		A measure of the inability of an image to reproduce parallel lines when parallel lines are presented at a target.
Electronic Medical Record	EMR	Overall system which is subject to DEA-EPCS regulations and which digitally signs and transmits electronic prescriptions
Electronic Prescription of Controlled Substances	EPCS	Program allowing physicians and their agents to electronically transmit prescriptions to a dispensary such as a pharmacy.
Enrollee		Person enrolling in the EMR
Factor		In authentication, one of the pieces of evidence that is used to support the identity claim of the claimant.
False Match Rate	FMR	Probability that the system incorrectly matches the input pattern to a non-matching template in the database
False non-match rate	FNMR	Probability that the system fails to detect a match between the input pattern and a matching template in the database
Failure to acquire	FTA	Failure to capture and/or extract usable information from a biometric sample
Failure to enroll	FTE	Failure to create a proper template from an input for a number of specified attempts (governed by NIST SP800-76-1)
Implementation under test	IUT	That which implements the standard(s) being tested
Institutional Review Board	IRB	A committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans
Independent Test Lab	ITL	Lab accredited by NIST to perform certification testing of biometric systems.
Logically Shred		To overwrite data in memory or disk locations enough times to mitigate the probability that the information can be retrieved by unauthorized persons
National Voluntary Laboratory Accreditation Program	NVLAP	Part of NIST that provides third-party accreditation to testing and calibration laboratories.
New England Independent Review Board	NEIRB	An independent institutional review board, ensuring the rights and welfare of research study participants
Operating point		Biometric systems can utilize a variety of algorithms and techniques to reach a decision as to whether a challenge biometric matches a previously enrolled biometric. The sum of all of these configuration parameters including some similarity score cutoff corresponds to the operating point of the system.
Principal Investigator	PI	Person responsible for the oversight of their research and ultimately responsibility for the conduct of those to whom they delegate responsibility
Personally Identifiable Information	PII	Any personal information about an individual, maintained by an agency, including, but not limited to an individual’s name; social security number; date of birth; mother’s maiden name; biometric records; education; financial transactions; medical history; criminal or employment history; and information which can be used to distinguish or trace an individual’s identity

Term	Abbreviation	Definition
PDF file	PDF	File format for all releases of the Report
Resolution		Used in the context of this report, refers only to the pixel width and height of a digitized image produced by a camera.
Software Development Kit	SDK	Set of software development tools which allows for the creation of application for a software package
Spatial Frequency Response	SFR	Estimation of the spatial frequency response of an imaging device based on an image of a slanted edge and line-spread-function of that image.
System under test	SUT	The computer system of hardware and software on which the implementation under test operates
Technology Testing		Refers to the acquisition of a corpus of biometric records that are used to enroll and challenge a biometric system to determine statistics such as false-match rate and false-non-match rate
Vendor		Biometric subsystem manufacturer

3.2 *DEA-EPCS Certification*

3.2.1 Definition of Test Criteria

The test criteria determined the configuration and test cases for execution. The 1Kosmos biometric application configurations were established in collaboration with the vendor.

The test requirements are established in the DEA Final Interim Rule specifically in 21 CFR 1311.116(b) and (h)(4) that require that the biometric subsystem operate at a point with 95% confidence that the false match rate is 0.001 or lower. iBeta utilized the test methods defined in ISO/IEC 19795-1 and ISO/IEC 19795-2 to acquire biometric data and used it to test the technology of the biometric subsystem to validate an operating point that met this requirement.

3.2.2 Test Environment Setup

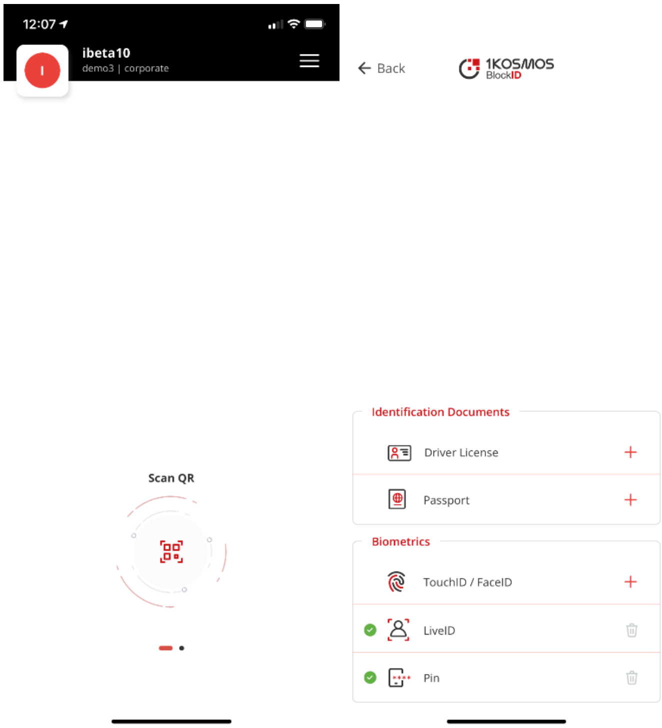
For this test effort, iBeta located all equipment in the Biometrics Lab of the iBeta facility.

A test dry run was conducted prior to full data collection. On 24 September 2021, three iBeta employees provided Personally Identifiable Information (PII) and a prototype test of the data collection test case was conducted. Each subject performed 3 zero-effort impostor attempts on 3 devices and then enrolled and performed 5 genuine verifications. The data analysis was conducted online without any errors.

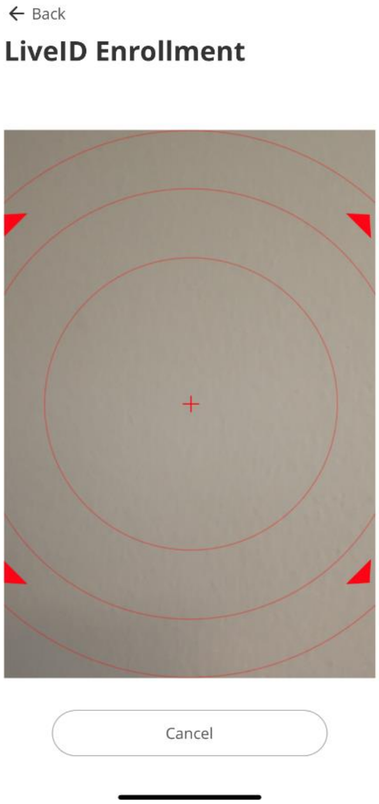
Prior to testing, all 10 devices were seeded with enrollments from iBeta employees so that the subjects were able to perform the zero-effort impostor attempts prior to enrolling themselves. Enrollment consisted of a single image capture from URLs provided by 1Kosmos and was conducted in normal office lighting (between 250 and 700 LUX).

Testing was done on ten total devices (iPhone XR, iPhone XS, iPhone 11, iPhone 11 Pro, iPhone 12 Pro Max, Google Pixel 3a, Google Pixel 4, Samsung Note 10, Samsung Galaxy S10, and Samsung Galaxy S10+).

Picture 3-1: 1Kosmos BlockID Application



Picture 3-2: Biometric Acquisition with the 1Kosmos EPCS app



Subjects' data was associated with a URL. All references to the subjects' data was destroyed when the BlockID application was deleted from the device which occurred after each subject's enrollment was replaced. Each subject provided their self-declared ethnicity, their birthday month and year, and gender.

During this data collection, iBeta recorded three Failure to Enrolls (FTEs) and 40 Failure to Acquires (FTAs) instances across the five Android devices, where the application was unable to recognize the subjects. iBeta recorded zero FTEs or FTAs across the five iOS devices.

BlockID FMR testing and analysis was conducted online that utilized a backend matching algorithm. Each challenge was reported as a true match (tm_i), true non-match (tn_i), false match (fm_i) or false non-match (fn_i). If there were then M challenges that were expected to not match, a pair of numbers can be calculated. In each case, a challenge was considered to be a transaction with one of the results above reported.

$$FMR = \frac{\sum_{i=1}^{N} fm_i}{N} \qquad (3.2.3-1)$$

Equation 3.2.3-1 is the calculated (or observed) FMR; however, the DEA EPCS regulations require a statistical 95% Confidence Interval for the operating point of the system.

Since there were no False Matches recorded, iBeta used the Rule of 3 defined in ISO 19795-1-2006[2007]: "The Rule of 3 addresses the question "What is the lowest error rate that can be statistically established with a given number N of independent identically distributed comparisons?" This value is the error rate p for which the probability of zero errors in N trials, purely by chance, is (for example) 5%. This gives:

$$p \approx 3/N \qquad (3.2.3\!-2)$$

for a 95% confidence level."

As described above, the subjects performed 30 total zero-effort impostor attempts (15 across the iOS devices, 15 across the Android devices). iBeta used the methods and formulas documented in ISO/IEC 19795-1:2021 using the variances of the above rates of Table 3-2.

Table 3-2 Claimed versus Measured Error Rates

N x Observed Error Rate	N x Claimed Error Rate	Minimum N for an Error Rate of 0.001
0	3	3000
1	4.8	4800
2	6.4	6400
3	7.9	7900
4	9.3	9300
5	10.6	10600
6	11.9	11900
7	13.2	13200

The matcher was operating as a black box and results were recorded and document real-time. There was no off-line matching that occurred for the assessment of the FMR.

The 1Kosmos dashboard provided either successful or unsuccessful access to subjects for FMR testing. All testing was conducted online.

3.2.3 Test Execution

Test enrollment or data collection was conducted 16 November through 9 December 2021.

Following the DEA Regulations 21 CFR Part 1311, subjects were enrolled and included iBeta employees and non-employees as per the iBeta DEA-EPCS Biometric Test Protocol approved by the New England Independent Review Board.

Subject biographical data was acquired on paper. Only an identifier, the Biometric ID (BID), connected the subject biographical data to the acquired biometric data.

The mobile devices enclosed the biometric device, which consisted of the front-facing camera and the 1Kosmos application associated with the SaaS back-end application. Acquisition of Technology Testing corpus data was acquired in an office type of environment consistent with the expected environment for prescribing practitioners.

A Failure to Enroll (FTE) rate not to exceed 15% was assumed in the data collection planning. iBeta observed 3 FTEs during Android testing, resulting in an FTE rate of 1.6% for the Android test effort, and 0 FTEs during iOS testing, resulting in an FTE rate of 0% for the iOS test effort.

The matching and analysis of the False Match Rate calculations were performed online.

As described in Section 3.2.2, the images were presented to the 1Kosmos mobile application and were then accessed via a QR code that was linked to the 1Kosmos dashboard to acquire the FMR results. Matching was conducted online through a backend service described in Table 4-1 below.

There were documentation issues identified in the review and that Discrepancy Report is provided in Attachment 1.

During the data collection portion of the test effort, iBeta experienced 40 Failure to Acquire (FTA) instances where the subjects were unable to capture their zero-effort impostor attempts.

3.2.3.1 *Deviations and Exclusions*

In accordance with iBeta Standard Operating Procedures, any deviations from or exclusions to the test method are documented, technically justified, authorized and accepted by the customer.

There were no deviations or omissions from the standards.

4 Biometrics System Identification

The 1Kosmos BlockID and SaaS server applications as specified in Table 4-1 and 4-2 were tested for this certification.

4.1 *Submitted Biometrics System Identification*

Table 4-1 contains the elements of the 1Kosmos applications.

Table 4-2 lists the laptop system definition that was used for this test effort that meets the minimum requirements as listed above. No other hardware test environment was utilized.

Table 4-1 Biometrics System Name and Version

Biometric System Name	Version
BlockID (iOS and Android)	BlockID v1.5.21
BlockID server configuration	PI_co_1.05

For the test effort, 1Kosmos did modify the backend configuration during testing due to weekly/bi-weekly deployments, but stated that this change did not impact the matching algorithm. Prior to data collection, iBeta confirmed that the SaaS would experience upgrades but the matching algorithm on the mobile application and the SaaS changes would not impact the test results.

Table 4-2 Biometric System Software with Hash of Back-End server application

Biometric System Name	Version
BlockID (iOS)	BlockID v1.5.21 (Build: 6194EA8F)
BlockID (Android)	BlockID v1.5.21 (Build: 618E58D0)
BlockID server configuration (prior to the start of the test effort)	Pl_co_1.05.01.1d1b54e6399ccc637abe098a7d80af3b37aad83a.16365584545
Block ID server configuration (after the conclusion of the test effort)	Pl_co_1.05.02.73b60b711c92f5567e767ff67d0c7d57dba7f0e1.1639104269983.R

4.2 *Biometrics System Test Environment*

The Biometric Subsystem Test Environment identifies the specific hardware and software that was used in the test environment in Tables 4-3 and 4-4, respectively.

Table 4-3 Biometrics System Test Hardware

Hardware	Firmware, Operating System & Version	Description
Apple iPhone XR	iOS: 14.6 Model Number: MT352LL/A Serial Number: F17XK0E3KXKV	Device used for data collection via Block ID application
Apple iPhone XS	iOS 14.2 Model Number: MT942LL/A Serial Number: C39XD8RMKPFP	Device used for data collection via Block ID application
Apple iPhone 11	iOS: 14.7.1 Model Number: MWL9LL/A Serial Number: FK1ZC5QHN72L	Device used for data collection via Block ID application
Apple iPhone 11 Pro	iOS: 13.0 Model Number: MWCH2LL/A Serial Number: DNPZ60HBN6XM	Device used for data collection via Block ID application
Apple iPhone 12 Pro Max	iOS: 14.2 Model Number: MGCH3LL/A Serial Number: F2LDLACJ0D41	Device used for data collection via Block ID application
Google Pixel 3a	Android Version: 10 Model: Pixel 3a Serial Number: 94NAY0RAGV	Device used for data collection via Block ID application
Google Pixel 4	Android Version: S Model: Pixel 4 Serial Number: 99261FFAZOOFBS	Device used for data collection via Block ID application
Samsung Galaxy Note 10	Android Version: 10 Model: SM-N970U Serial Number: R58MA3151JK	Device used for data collection via Block ID application
Samsung Galaxy S10	Android Version: 11 Model:SM-G973U1 Serial Number: RF8M30GGAED	Device used for data collection via Block ID application
Samsung Galaxy S10+	Android Version: 10 Model: SM-G975U1 Serial Number: R58M32RZA8H	Device used for data collection via Block ID application

Table 4-4 Biometrics System Test Software

Hardware	Firmware, Operating System & Version	Description
HP Laptop	Model: 15-dy1xxx Windows 10 Device ID: 93415569-C7F1-4BC4-B2BA-E07F179C632B	Used to access the dashboard from a QR code to obtain pass/fail results
Lenovo Laptop	Model: ideapad 320-15IKB Windows 10 Device ID: 2DFE7DFF-4213-43EA-9F43-538C326AC470	Used to access the dashboard from a QR code to obtain pass/fail results

1Kosmos Block ID Workforce Dashboard	Demo Site v0.9.0 URL: https://demo.1kosmos.com/workforce	URL used to access the dashboard from a QR code to obtain pass/fail results

Table 4-5 Biometrics System Technical Documents

Version #	Title	Date	Author (Org.)
1.0	BlockID – Architecture.pptx	9/30/2021	1Kosmos

Throughout the test effort, iBeta utilized other software, hardware and materials as warranted to support the testing, analysis and reporting.

Table 4-6 Other Software, Hardware and Materials

Material	Material Description	Use in the Biometrics System
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	TDP and 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
Traceable® Digi-Sense Light Meter	Ambient light meter S/N: 181729938	Ambient light measurements were taken prior to biometric data acquisition on a per day basis or when conditions change

4.2.1 Biometrics Test Environment – Technology Test

The devices listed in Table 4-3 indicate their functional purpose in the test effort. Ten devices were used to capture all of the data for the testing (iPhone XR, iPhone XS, iPhone 11, iPhone 11 Pro, iPhone 12 Pro Max, Google Pixel 3a, Google Pixel 4, Samsung Galaxy Note 10, Samsung Galaxy S10 and S10+). All subjects performed 30 total zero-effort impostor attempts (3 on each device – 15 total on the five iOS devices, 15 total on the five Android devices). Subjects then performed enrollments (1 on an iOS device and 1 on an Android device), followed by 5 verification transactions (5 against the iOS device's enrollment and 5 against the Android device's enrollment).

4.2.1.1 *Processing and Post-processing*

All results were recorded online.

5 Biometrics System Overview

The 1Kosmos biometric subsystem consists of the BlockID mobile application and the front-facing camera.

The test conducted for DEA EPCS certification consisted of a data collection application that drove the sensor for image capture. Additional functionality of the biometric subsystem was reviewed to verify additional requirements of the DEA EPCS regulations in addition to the FMR (1311.116(b)) requirement.

As tested, the enrollment and verification subsystem accessed the records through the filesystem. iBeta was not able to review any other functionality associated with a specific implementation of the biometric subsystem as it might interface to an EPCS certifiable system.

iBeta only reviewed the functionality of this system as it relates to the DEA EPCS regulations as it pertained to those described in this report and specifically to the 1311.116 section.

6 Certification Review and Test Results

The results and evaluations of the certification are identified below. Detailed data regarding the Acceptance/Rejection criteria, reviews and tests for FMR are found in Attachment 1 (not released publically).

6.1 *Limitations*

The results and conclusions of this report are limited to the specific Implementation under Test (IUT) applications and versions described in Section 1.1 and Section 4.1.

It was the responsibility of 1Kosmos to provide iBeta with the application and documentation for certification which are representative of those systems and devices produced for the consumer. iBeta used devices from our equipment inventory to conduct the test effort.

These results represent usage of falsification testing methodology. Testing can only demonstrate non-conformity, i.e., if errors are found, non-conformance of the IUT 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 IUT conforms to the regulations. Use of these results will not guarantee conformity of an implementation to the regulations; that normally would require exhaustive testing, which is impractical for both technical and economic reasons.

During pre-engagement and pre-assessment analyses, iBeta determined that the 1Kosmos biometric subsystem could be built into an EPCS system. The interface to the device is an API, however, iBeta tested the BlockID SaaS back-end application through vendor supplied applications (apps). Much of this configuration could vary in a final EPCS implementation. The interface to the file system of enrollment records also depends on physical and logical security of the overall system.

The scope of this iBeta report and certification is solely for the 1Kosmos biometric subsystem using images acquired using the 1Kosmos system. The evaluation and testing certifies that the 1Kosmos system meets the DEA biometric regulations and can be incorporated into an EPCS application which can then be certified to meet the full DEA EPCS regulations.

6.2 *DEA Biometric Subsystem Review*

6.2.1 1Kosmos Component Results

There were neither deviations from the DEA approved test method nor any test setup that varied from the standard protocol. The results are reported in detail in Attachment 1 (not publicly available) to this report.

False Match Rate results are given in Section 6.3.

6.2.1.1 *Exceptions*

There were no exceptions taken to the test method.

6.3 *False Match Rate Review*

As described in the Test Environment Setup Section 3.2.2 above, the False Match Rate (FMR) was calculated based on results from approximately 3,000 attempted matches on iOS with 191 subjects enrolled and 2,880 attempted matches on Android with 188 enrolled subjects. Of those matches, 955 were expected to match on iOS and 940 were expected to match on Android.

iBeta obtained the Age (Table 6-1), Gender (Table 6-2), Ethnicity (Table 6-3), and Facial Attributes (Table 6-4) demographics reported below.

Table 6-1 Age Demographics

Age (Years)	Count	Percentage
<18	0	0.0%
18 – 35	61	30.5%
36 – 52	81	40.5%
53 - 70	57	28.5%
70>	1	0.5%

Table 6-2 Gender Demographics

Gender	Count	Percentage
Male	95	47.5%
Female	105	52.5%
Undisclosed	0	0.0%

Table 6-3 Ethnicity Demographics

	Count	Percentage
White	121	60.5%
African American	26	13%
Hispanic	24	12%
Asian	20	10%
Other	9	4.5%

6.3.1 Exceptions

The 1Kosmos biometric subsystem is certified effective on the publish date of this report. Per 21 CFR 1311.300(a)(2), this certification expires 2 years from that date. Also per that requirement, the assessments and testing for certification applies only to the subsystem tested and documented within this report. Any alterations to that subsystem invalidate this certification.

The data supporting these certification results are found in Attachment 1.

6.4 *Other EPCS Biometric Subsystem Requirements*

Table 6-4 Testing of Biometric Subsystem Requirements

Requirement Reference	Requirement	Details of level of iBeta Assessment	✓
1311.116(a)	If one of the factors used to authenticate to the electronic prescription application is a biometric as described in § 1311.115, it must comply with the following requirements.	The purpose of this report is to allow that the facial biometric as obtained and described herein meets the other subsystem requirements for use in a DEA EPCS system.	☑
1311.116(b)	The biometric subsystem must operate at a false match rate of 0.001 or lower.	As described in section 6.3, the application and device meet this requirement.	☑
1311.116(c)	The biometric subsystem must use matching software that has demonstrated performance at the operating point corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate. Testing to demonstrate performance must be conducted by the National Institute of Standards and Technology or another DEA-approved government or nongovernment laboratory. Such testing must comply with the requirements of paragraph (h) of this section.	The purpose of this report is to validate the threshold required to produce a FMR or 0.001 or lower. iBeta is a DEA-approved nongovernment laboratory. The system certifying agency must verify that the algorithm operates at the threshold defined above.	☑
1311.116(d)	The biometric subsystem must conform to Personal Identity Verification authentication biometric acquisition specifications, pursuant to NIST SP 800–76–1 as incorporated by reference in § 1311.08, if they exist for the biometric modality of choice.	Not Applicable	☑
1311.116(e)	The biometric subsystem must either be co-located with a computer or PDA that the practitioner uses to issue electronic prescriptions for controlled substances, where the computer or PDA is located in a known, controlled location, or be built	The biometric device (smartphones) is expected to be co-located with the practitioner's smartphone.	□

Requirement Reference	Requirement	Details of level of iBeta Assessment	✓
	directly into the practitioner's computer or PDA that is used to issue electronic prescriptions for controlled substances.		
1311.116(f)	The biometric subsystem must store device ID data at enrollment (i.e., biometric registration) with the biometric data and verify the device ID at the time of authentication to the electronic prescription application.	1Kosmos was able to show that the subsystem is storing the device ID data during enrollment and verifying the device ID at authentication; however, this requirement will need to be fully testing in the overall EPCS system.	□
1311.116(g)	The biometric subsystem must protect the biometric data (raw data or templates), match results, and/or non-match results when authentication is not local. If sent over an open network, biometric data (raw data or templates), match results, and/or non-match results must be: (1) Cryptographically source authenticated; (2) Combined with a random challenge, a nonce, or a time stamp to prevent replay; (3) Cryptographically protected for integrity and confidentiality; and (4) Sent only to authorized systems.	The scanned copy of the data (facial image) is stored on the mobile device. The data is encrypted using a private key unique to the users which is on their mobile device and the encrypted copy of the data is captured on the blockchain. Since it is stored on the blockchain, 1Kosmos cannot delete the data' however, all references to the blockchain (pointers) are shredded such that all reference to that data is lost. This requirement may need to be fully tested in the overall EPCS system.	□
1311.116(h)	Testing of the biometric subsystem must have the following characteristics: (1) The test is conducted by a laboratory that does not have an interest in the outcome (positive or negative) of performance of a submission or biometric. (2) Test data are sequestered. (3) Algorithms are provided to the testing laboratory (as opposed to scores or other information). (4) The operating point(s) corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate, is tested so that there is at least 95% confidence that the false match and non-match rates are equal to or less than the observed value. (5) Results of the testing are made publicly available.	(1) iBeta is independent of 1Kosmos and does not have an interest in the outcome of the performance of this testing. (2) Test data were destroyed at the conclusion of testing and test data were not provided to the vendor during testing. (3) The BlockID application was connected to a cloud-based service where the matching algorithm was hosted. (4) iBeta's process and procedures to test the FMR at 95% confidence have been approved by the DEA. (5) This report is available at http://www.ibeta.com/our-software-quality-services/epcs/reports/	☑

6.4.1.1 *Exceptions*

The 21 CFR 1311.116(g) requirements were not tested as iBeta only had access to the matching algorithm and no means to connect that algorithm to a system that might operate like an EPCS approvable system. iBeta verified that the BlockID v1.5.21 could be incorporated into an enclosing or encompassing Electronic Health Record application that would then meet the requirements.

7 Opinions and Recommendations

7.1 *Recommendations*

iBeta Quality Assurance has completed the testing of the 1Kosmos BlockID biometric subsystem. In our opinion the acceptance requirements of 21 CFR Parts 1311.116 have been met as delineated in Table 7-1 and its Notes.

iBeta Quality Assurance certifies the BlockID application to the requirements of 21 CFR Parts 1311.116(b) and 1311.116(h)(4). Other requirements assessed are also included below in Table 7-1.

The following table (Table 7-1) contains the 21 CFR 1311 requirements that were found to be in compliance with the regulation. Requirements checked (☑) were found to be in compliance. Requirements not checked (□) were not within the scope of iBeta's certification and must be tested by the entity certifying or auditing the overall EPCS system as described in the Notes. However, in all cases, iBeta believes this system can be incorporated into an EPCS certified system to meet all requirements for that system.

Table 7-1 Requirement in Compliance

Requirement	Description	Approved
1311.116(a)	If one of the factors used to authenticate to the electronic prescription application is a biometric as described in §1311.115, it must comply with the following requirements.	□
1311.116(b)	Biometric subsystem to operate at a false match rate of 0.001 or lower	☑
1311.116(c)	The biometric subsystem must use matching software that has demonstrated performance at the operating point corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate. Testing to demonstrate performance must be conducted by the National Institute of Standards and Technology or another DEA-approved government or nongovernment laboratory. Such testing must comply with the requirements of paragraph (h) of this section.	☑
1311.116(d)	The biometric subsystem must conform to Personal Identity Verification authentication biometric acquisition specifications, pursuant to NIST SP 800–76–1 as incorporated by reference in § 1311.08, if they exist for the biometric modality of choice. *This standard does not apply to the system under test.	☑
1311.116(e)	The biometric subsystem must either be co-located with a computer or PDA that the practitioner uses to issue electronic prescriptions for controlled substances, where the computer or PDA is located in a known, controlled location, or be built directly into the practitioner's computer or PDA that he uses to issue electronic prescriptions for controlled substances.	□
1311.116(f)	The biometric subsystem must store device ID data at enrollment (i.e. biometric registration) with the biometric data and verify the device ID at the time of authentication to the electronic prescription application.	□

1311.116(g)(1)
1311.116(g)(2)
1311.116(g)(3)
1311.116(g)(4)
	The biometric subsystem must protect the biometric data (raw data or templates), match results, and/or non-match results when authentication is not local. If sent over an open network, biometric data (raw data or templates), match results, and/or non-match results must be:
	Cryptographically source authenticated, combined with a random challenge, a nonce, or a time stamp to prevent replay, cryptographically protected for integrity and confidentiality; and sent only to authorized systems.
		□

Requirement	Description	Approved
1311.116(h)(1)	The test is conducted by a laboratory that does not have an interest in the outcome (positive or negative) of performance of a submission or biometric.	☑
1311.116(h)(2)	Test data are sequestered.	☑
1311.116(h)(3)	Algorithms are provided to the testing laboratory (as opposed to scores or other information).	☑
1311.116(h)(4)	The operating point(s) corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate, is tested so that there is at least 95% confidence that the false match and non-match rates are equal to or less than the observed value.	☑

All other 21 CFR 1311 requirements that may be applicable to an installed biometrics subsystem were outside of the scope of testing of this subsystem in the absence of its containing system. All other requirements must be tested for the overall enclosing system.

Notes on the 1311.116 requirements:
(a) 1311.116(a) is a rollup requirement mandating the other requirements for biometrics subsystem
(e) The tested biometric subsystem has the capability to meet this requirement but it must be tested for the overall system. See Table 6- for details.
(f) The tested biometric subsystem has the capability to meet this requirement, but it must be implemented and tested for the overall system. See Table 6- for details.
(g) The tested biometric subsystem has the capability to meet this requirement especially when operated locally. See Table 6- for details.

7.1.1 Limitations

As described in Section 6.1 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 regulations. Device or system behavior which falls outside of the scope of this testing is not certified. iBeta cannot extrapolate the results of the testing to include devices other than those listed in Table 1-1.

Because the biometric subsystem does not sign or receive electronic prescriptions, it was found to not be subject to other requirements of the 21 IFR Part 1311 such as auditing and records maintenance. These are the responsibility of the overall system since the biometric subsystem only returns a successful/unsuccessful response to one of the two factors used for authentication prior to signing a prescription.

As shown in Table 6, the FMR requirement of 0.001 at a 95% Confidence Interval is met with an Operating Point of 2.8.

One of the purposes of this report is to evaluate the threshold or operating point at which the biometric authentication method meets the 0.1% FMR mandated by the DEA EPCS regulations. The regulations specify the use of 95% confidence interval applied to the observed measurements. There may be other sources of measurement error over which iBeta had no control. Most likely, these sources would affect FNMR to a greater extent than FMR.

7.1.2 Exceptions

There were no exceptions other than those listed in Section 6.3.1.

7.2 *Opinions*

The vendor supplied documentation was acceptable for iBeta to produce a software test suite built upon the vendor’s application.

The BlockID v1.5.21 application operated as expected.

7.3 *Responsible Test Laboratory Personnel*

The responsible test laboratory person and the contact information for the New England IRB appointed Principal Investigator for this test effort:

Gail Audette

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