

Apollo BioTech™

Apollo eXpress

Intelligent Analyzer

iaX-2101

User Manual



assaya 
Universal Mass RAPID Testing



Symbols

ISO 15223-1 Medical Devices – Symbols that are found on the Device Labels

Symbol	Explanation	Referent
	Manufacturer	Apollo BioTech co., ltd. 18F-1 No. 75 Xintai 5th Road, Xizhi 22101 New Taipei City, Taiwan
	Fragile, handle with care	Be careful when transporting, unpacking, using and storing this product. Do not drop!
	Catalogue Number	iaX-2101
	Serial Number	iax-2010-xxxxxxxx
	Keep Dry	Do not expose to moisture or liquids
	Temperature Limitation	5C to 30C
	Humidity Limitation	10% to 90% RH
	Consult Manual for use	Read this manual before you use this product
	Caution	Improper use of this product may result in misdiagnosis of disease thus risk to human lives
	Electrical Hazard - Do Not Open	This product contains electrical parts that can cause harm if touched.
	In Vitro Diagnostic medical device	This product may be used in combination with IVD test kits for diagnosis of disease.

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Introduction

This manual describes how to install, operate and troubleshoot the Apollo eXpress Intelligent Analyzer hereafter called “iaX” for short. Before using the iaX, it is essential that you read this manual carefully and pay particular attention to the safety information.

Overview

The Apollo iaX is part of the Apollo Complete Testing Solutions (ACTS). The iaX can read Lateral Flow Assay (LFA) Colorimetric and Immunofluorescence Assays. The reader is an intel™ based hardware platform with Ubuntu software running the testing application, and an Amazon Web Services (AWS) cloud computing backend solution that collects the test data in real time. The data can then be analyzed and processed by 3rd party ecosystem partners, such as testing facilities, regulatory agencies, etc.

The iaX does NOT collect and store ANY patient data. Every test is tracked only through a serialized barcode. It is up to ecosystem partners to correlate the unique serial number for each test with a patient record.

The iaX was designed to be able to read test results from a wide variety of LFAs type cassettes and cards from many vendors. It can identify features of samples, such as bar codes, QR codes, and data matrices, which is then used to identify the vendor and type of the particular test inserted. The iaX can support any number of testing profiles unique for each vendor and type cassette, so that many types of tests for various pathogens can be supported.

The iaX is the only reader that can read Apollo BioTech’s own test kits, both using traditional cassettes as well as using the ClearAssay and CleaReagent technologies.

Intended Use

Please note that the intended use may vary between test kits and the operator should always ensure to read and follow the instructions and documentation for the specific test to be performed, both in collecting the sample and preparing the sample for analysis by the iaX.

The Apollo iaX and the test kits described herein are only intended for in vitro diagnostic use, and should only be used by personnel that have read and understood this manual, and received proper training in the use and operation of the iaX.

Some tests are limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Please refer to the section in this document describing each of the supported tests in detail and ensure that the operator observes the requirements for each test specifically.

General Information

The Apollo iaX tests for the presence of wide variety of pathogens in 3 easy steps:

1. A specimen is collected from a patient
2. A reagent is combined with the specimen and develops inside a single use vessel
3. The vessel is inserted into the iaX, which reads and reports the results instantly

The Apollo iaX uses a camera and a complex lightsource that consists of multiple LEDs with specific wavelengths that are illuminated in a particular sequence specific to each test. LEDs range from infrared, through visible and ultraviolet light.

The Apollo iaX first determines the type of test inserted, and then uses a stored profile for that particular test, which contains parameters for LED wavelength, position and intensity, along with camera profile settings that have been developed for that particular test. The profile also contains thresholds for how results shall be reported.

The combination of the camera and the illumination by LEDs far outperform reading tests visually to determine results by human eye, as it is not subject to personal interpretation, achromatopsia (color blindness), myopia, hypermetropia, astigmatism, ambient lighting conditions, glare of glasses, glare from fluorescent lighting, or overexposure from sunlight or other artifacts from natural and artificial lighting sources.

Using this technology ensures that optimal lighting conditions and camera settings are selected every time for every single test, which facilitates secure and consistent reading of test results every time for every test.

How it works

The Apollo iaX uses a camera and a light source to continuously capture images of the area where tests are inserted. The camera is a fixed focus HD resolution camera that captures raw data for video processing by the software running locally in the iaX. The light source is a combination of many LEDs with various wavelengths ranging from ultraviolet through visible light and Infrared. All testing is done visually, and there are no mechanical switches in the iaX for detecting inserted tests, which improves durability.

The software running in the iaX has full control over the camera settings and the brightness of each LED, which allows the iaX to be configured to detect a wide variety of tests from a multitude of vendors. As more and more tests get approved and enter the market, the iaX connects to a central cloud database to get updates for new test types.

Because the camera and lighting parameters all programmable on-the-fly and so tightly controlled, the iaX allows for tests to record qualitative measurements of test results for use in statistical analysis by professionals, while at the same time providing an instant simple threshold based Positive or Negative result readout on the front of the machine itself to the tester.

The test result is displayed for as long as a valid test is held in the machine, and clears when the test is removed from the machine. The iaX periodically sterilizes the test area automatically using ultraviolet UVC type LEDs. This is done automatically.

Safety Information

Before using the iaX it is essential that you read this user manual carefully and pay close attention to the safety information described in this chapter. The instructions in this manual must be followed to ensure the safe operation of the iaX itself and particularly to ensure that the results of the tests being performed are accurate.

Even one single test that is performed incorrectly and shows an incorrect result can cause substantial inconvenience, serious conditions and situations for the individual, for healthcare workers, other personnel, family members and put the general population at risk of contracting and spreading diseases.

Electrical Safety

This machine contains electrical components that can cause serious injury or death if touched. Please take care to avoid any damage to the personnel operating the machine.

- DO NOT OPEN the machine or any part of the accessories.
- DO NOT insert any tools, metal objects, sharp objects or any other objects specified in this manual as supported safe to use with this testing system.
- DO NOT submerge the unit or any parts of the unit in water or any other liquid, including solvents or cleaning liquids.

Biological Safety

This machine can test specimens from humans or animals that may be collected from tissue, blood, urine, other bodily fluids or feces. Even though all biological samples should remain in their testing vessels during the entire operation, and should never come directly in contact with any part of the machine itself, operators must take care to ensure that any spillage of biological materials, chemical reagents, samples, or other consumables never come in direct contact with the operator or the machine itself.

Personal Protective Equipment (PPE)

Always wear proper PPE when collecting specimens from humans, animals or laboratory samples. Always follow the guidelines for use of proper PPE depending on which type of test is being performed and which pathogens that could be presented in the specimens.

Cross-contamination Avoidance

Always be careful to observe that consumables that are used with the machine are free of any damage, rupture, breaks, tears, or other faults that may cause spillage and potential contamination of the machine and its accessories. Spillage of biological samples may cause cross contamination of consecutive specimens, and thus may present false results.

Personal Data Protection

The Apollo iaX does not with its basic feature set described in this manual collect, retrieve or store any personal information or data about any person, patient, or tester. The data

collected for each test is limited only to the information found on the data matrix, barcode or QR code found on the tests themselves and the test results themselves.

If in the future accessories are approved for use with the iaX to specifically collect personal data, drivers license information, ID cards, Health Record Cards, etc. a separate operation manual will address Personal Data Protection for those use cases.

Operation

The following section describes the operation, configuration and maintenance of the iaX.

Calibration

The Apollo iaX is self calibrated and does not require any user input or interaction to ensure proper operation.

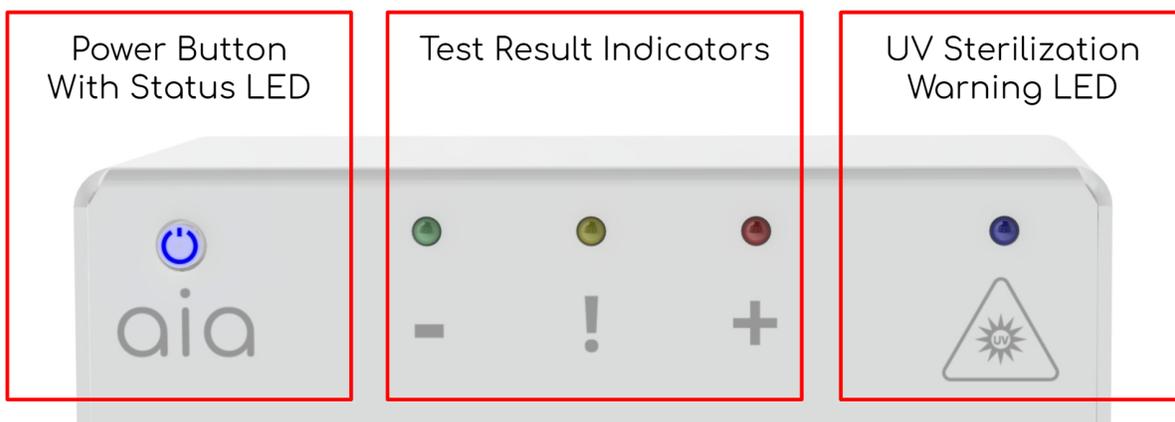
Software Updates

The Apollo iaX checks for new software patches, security patches or updates to the Apollo Reader Application during these events:

- Every time the machine boots
- Once every 24 hours when testing has been idle for approximately 1 hour

Power Button and Status Indicator

The picture below shows the 3 sections for the front of the iaX and their function:



To power up the unit:

Push the Power Button briefly ONCE and wait for the BLUE LED to become steady.

Power Up Sequence

The iaX Power LED has the following states:

Blue LED	Status	Illustration
OFF	Machine is OFF	LED is OFF 
Blinking	Machine is booting	LED is BLINKING
Steady ON	Machine is READY	LED is ON 

Result indicator LEDs

The test will show the status LED for as long as the test cassette is inserted. When the cassette is removed the LEDs will turn off and the iaX is ready for a new test. The front of the iaX has 3 LEDs that indicate the possible test results as follows:

- Negative (GREEN)



! Invalid (YELLOW)



+ Positive (RED)



Networking Connections

For proper operation the iaX must be connected to the Internet.

If a connection cannot be detected, the machine will still operate, but result data will not be transmitted to the cloud.

<p>A RED LED indicates problems with the network connection.</p> <p>This happens if neither the Wired LAN or the Wireless LAN has a connection to the Internet.</p> <p>See below how to set up Networking for the iaX</p>	
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Using Wired LAN:

- 1) Ensure that one or more LAN ports are connected to a switch or router that is connected to the internet.
- 2) For wired LAN ports, the Green/Yellow LEDs on the RJ-45 connectors will indicate activity, so make sure these are blinking if you are using Wired LAN.

Using Wireless LAN (WiFi)

- 1) Make a hotspot or Wireless Network Access Point
- 2) Make sure the iaX is within reach of the Wireless Access Point
- 3) If the RED LED on the iaX does not disappear after a few minutes:
 - a) Press the power button to shut down
 - b) Wait for the iaX to power off (power button is dark)
 - c) Press power button again to power up
 - d) Wait a few minutes

The wireless network should be configured as follows:

Network Name (SSID)	Assaya
Authentication Method	WPA2-Personal
WPA Encryption	AES
WPA Pre-Shared Key (Password)	88888888

Sterilization

The Apollo iaX contains UVC (Ultraviolet 275 nm) LEDs that are automatically engaged when the machine needs to be decontaminated. This happens automatically and typically happens every time the machine is shut down (power button is pushed).

The sterilization cycle time depends on which organisms or pathogens have been tested and the test result. When the sterilization cycle is active, the Blue LED next to the UV warning label is illuminated.

WHEN THIS LIGHT IS ON:

- DO NOT USE
- DO NOT UNPLUG
- DO NOT LOOK INTO THE OPENING
- DO NOT INSERT ANY OBJECTS OR VESSELS



Troubleshooting

Please follow the suggestions from the table below to resolve particular conditions that may occur. If any problems still occur please contact your Apollo distributor for service.

Condition	What to do
Suspicious frequency of invalid tests	1) Power down the unit by pushing the power button and waiting until the Blue Power LED turns OFF 2) Remove the Power Cable 3) Remove the Carrier 4) Clean the Carrier 5) Clean the Interior 6) Let all cleaned parts dry 7) Reinstall the carrier 8) Add Power Cable 9) Wait for the Blue Power LED to stop blinking and turn steady ON
None of the Result LEDs illuminate when tests are inserted	
All 3 result LEDs are flashing together	

Maintenance

There are no user serviceable parts inside. DO NOT EVER OPEN THE MACHINE. Opening the machine voids the warranty, and may violate a license agreement to use and operate the machine. Opening the machine or tampering with the camera or LED illumination board can cause permanent damage to the machine and result in false test results.

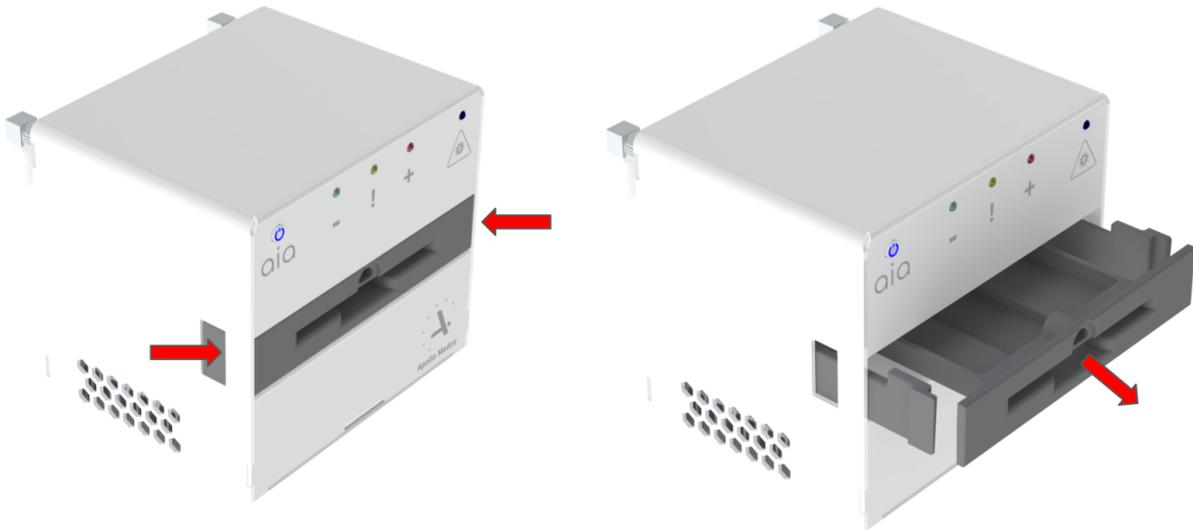
Exterior Cleaning

Clean the exterior of the iaX by spraying 75% laboratory grade Ethanol, and wipe down with a soft cloth.

Carrier Removal

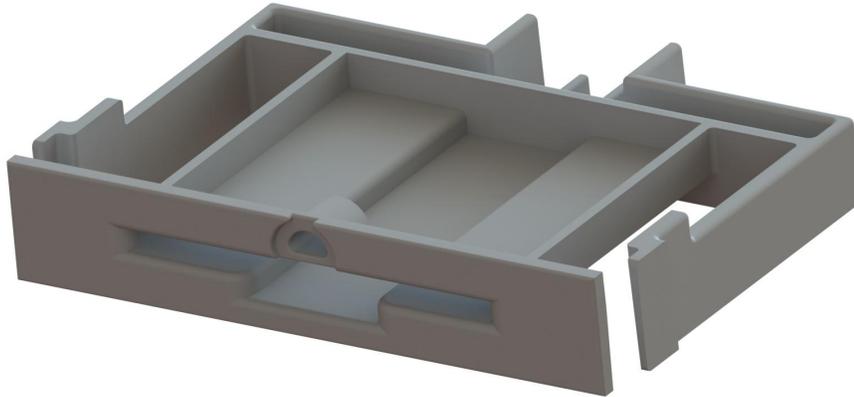
To remove the carrier for cleaning, follow the instructions below:

- Pop the carrier out by pressing in the tabs on both sides of the iaX simultaneously
- Pull the carrier all the way out by hand



Carrier Cleaning

After removing the carrier, place it on a flat surface and spray with 75% laboratory grade Ethanol. Wipe exposed areas with a cloth and repeat until all stains or spillage has been removed. Note that the carrier may have a different color than the one shown in the picture.



Interior Cleaning

Use the following procedure to remove dust and debris from the camera and LED illumination board:

- Turn off power!
- Remove the Carrier
- Blow compressed air from a can

If the compressed air spray can come with a nozzle, do not use it, and only use the can sprayer itself. Only blow air from the outside in. Be careful not to touch any components inside the machine!

DO NOT SPRAY ANY SOLVENTS OR CHEMICAL CLEANERS!



Testing

The following table compares 3 popular testing methods used in In Vitro testing:

Test Type	iaX Supported	POC *) Suitable	Typical Sample Collection Method
Rapid Antigen	Yes	Yes	Nasal swab
Rapid Antibody	Yes	Yes	Blood/serum
RT-PCR *)	No	No	Nasopharyngeal

*) PCR = Polymerase Chain Reaction, POC= Point Of Care

Note from the table that the iaX can perform both Rapid Antigen and Rapid Antibody testing using Lateral Flow Assay when used with suitable cassettes, cards or strip containers.

The iaX can test many types of cassettes from many vendors. This document does not cover a specific test to be used with the machine but offers general information on the use and operation of the machine.

Please refer to the Apollo website for an up-to-date list of currently approved tests !

Understanding the Results

This section explains how to consider test result outcomes, and what precautions shall be taken when considering the test results themselves.

Infected vs infectious

An "infected" patient is a patient where a particular pathogen exists within its system, and where the pathogen may or may not be replicating at a particular time, and where the patient may or may not be showing any signs of being infected.

An "infectious" patient is a patient that has the ability to infect others, typically as a result of an infection.

Please keep in mind that:

- A patient who is "asymptomatic" (who does not present with any symptoms) may still be infected.
- An infection may not present any symptoms in the early stages of the infection or may never present any symptoms.
- An infected patient may or may not be "infectious" (have the ability to infect others)
- A patient's ability to infect others may change over the course of the infection
- An "infectious" patient who is actively shedding a pathogen, may not be producing enough infectious material at a particular time during an infection for samples taken to be detectable with a positive result.

As a result of this, Lateral Flow Assay (LFA) type tests and Viral Antigen Rapid Tests (VART) type of tests will only indicate a positive result if:

- A patient is currently "infectious" and is actively producing infectious material

- The patient was properly prepared before collecting the sample
- The sample was taken correctly
- Sufficient amount of infectious material was collected within the sample
- The sample was properly prepared prior to being dispensed on the testing medium
- The sample was not contaminated or excessively diluted
- The correct amount analyte was dispensed on the testing medium
- The testing medium was handled properly, and used before its expiry date
- The test was allowed enough reaction time to fully develop
- Test machine reading the test was properly configured and properly maintained

What is an INVALID (!) result

Tests that present with an invalid result are usually caused by one or more of the following conditions:

- Not enough buffer or sample prep was used
- Too much buffer or sample prep was used
- The patient did not properly prepare for the test by cleaning their nose, and provided excessive amounts of mucus in the sample
- The cassette was not used immediately after having removed it from the pouch, or was expired, or damaged in any other way.

What is a NEGATIVE (-) result

A test that presents with a Negative result is not proof that the patient tested is indeed entirely free of the pathogen tested for. What it means is that the pathogen tested for was not detected in the sample taken in a significant enough amount to produce a positive result.

What is a POSITIVE (+) result

A test that presents with a Positive result is an indication that the sample taken contains the pathogen tested for in enough quantity to cause a chemical reaction detectable above the sensitivity level of the test system.

What to do if a patient tests positive

- Do not panic !!
- Double confirm once again that proper PPE is being used by all testing personnel
- Follow local guidelines for handling a patients and report the results to the proper local authorities
- Determine based on local policy if the patient should take another type of test (such as PCR) to confirm the result
- If applicable, explain the result to the patient, and provide guidance for quarantine or isolation according to local regulations.
- Decontaminate items and surfaces in the vicinity or potentially touched by patient

Tests types supported

The Apollo iaX supports many types of cassettes and cards. Below shows examples of such devices.

Examples of Test Types
SARS Covid-19
Influenza A+B
Respiratory Syncytial Virus (RSV)
SARS Covid-19 Antibody IgG/IgM

Examples of Vendors
Apollo BioTech™
BD™ (Becton, Dickson and Company)
Quidel™ (Quidel Corporation)
Abbott™

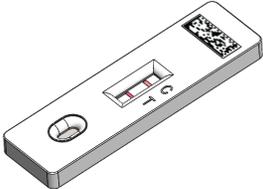
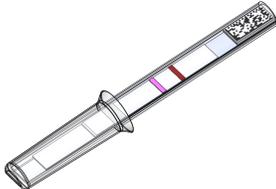
Note that the list of Test Types and Vendors above are examples only of the capability of the Apollo iaX to read tests from many vendors, and that it is not described in this manual how to conduct specific tests other than the test from Covid-19 from Apollo BioTech.

PLEASE READ THE "INSTRUCTIONS FOR USE" MANUAL FOR THE SPECIFIC TEST YOU ARE USING CAREFULLY!

Please contact Apollo BioTech regarding the up-to-date status of which FDA or EUA approvals have been granted for use of the Apollo iaX with the various Test Types and Vendors.

Supported Cassettes Types

The Apollo iaX can support 3 types of cassettes:

Traditional	Card	ClearAssay™
		

All cassette types supported by the Apollo iaX must have a visible barcode that is unique and that describes the type of test used. Test cassettes are inserted into the front of the iaX into the illuminated sample slot. Tests are automatically identified and read when inserted, and the result is shown for as long as the cassette remains inserted into the product.

THE FOLLOWING SECTION IS AN EXAMPLE ONLY!

PLEASE REFER TO THE
“INSTRUCTIONS FOR USE”
FOR THE ACTUAL TEST YOU WILL BE USING

Typical Test Procedure Example for Antigen Rapid Testing

The instructions below are general use guidelines for the Apollo iaX's use with typical LFA test cassettes and the specific example in this manual uses the SARS Covid-19 Ag test from Apollo BioTech as example.

Any test using the Apollo iaX consists of 3 parts that must be performed in sequence:

Part	Activity	Description	Procedure
1	Specimen Collection	Using a nasal swab to collect specimen from a patient	Depends on the type of test performed
2	Specimen Development	Preparing the specimen for being read by the iaX	Depends on the type Cassette used
3	Specimen Analysis	Reading the specimen with the iaX	Depends on the type Cassette used

1. Specimen Collection

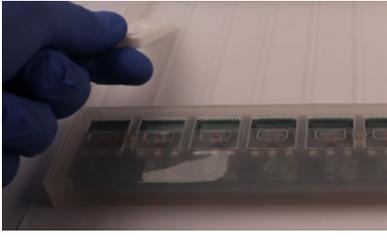
Follow the procedure below as illustrated and described.

Clean	Collect Right	Collect Left
		
<p>Ask patient to blow their nose using tissue paper to remove mucus, dust, and particles</p>	<p>Insert swab 2.5cm (1 inch) from the edge of the nostril and roll 5 times alongside the mucosa</p>	<p>Change to the other nostril and repeat the procedure of rolling 5 times alongside the mucosa</p>

Uncap	Plunge	Add Dispensing Cap
		
<p>Open the Extraction Buffer and Discard the Yellow Cap</p>	<p>Plunge for 30 seconds, then squeeze out and discard the swab</p>	<p>Place the Dispensing Cap. No need to twist or screw</p>

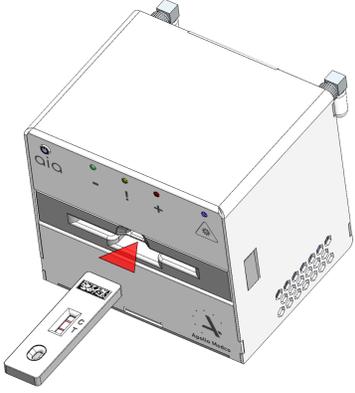
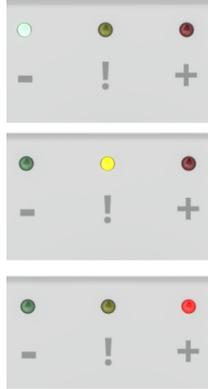
2. Specimen Preparation

Follow the procedure below as illustrated and described.

4 Drops	Develop	Wait
		
<p>Gently apply 4 drops onto the analyte pad of the LFA</p>	<p>Place the Cassette in the Apollo Timer Tray, and push the button</p>	<p>Allow 15 minutes for the test to complete its development</p>

3. Specimen Analysis

Follow the procedure below as illustrated and described.

Insert Cassette	Until it stops	Read Result
		

Tests have 3 possible Results:

Negative	Invalid	Positive
		
<p>The Patient is NEGATIVE</p>	<p>Something went wrong with the test, or the results are ambiguous. Please RE-TEST!</p>	<p>The Patient is POSITIVE</p>

Adverse effects reporting

If you are experiencing any anomalies with the iaX reader, testing kits, accessories, etc.

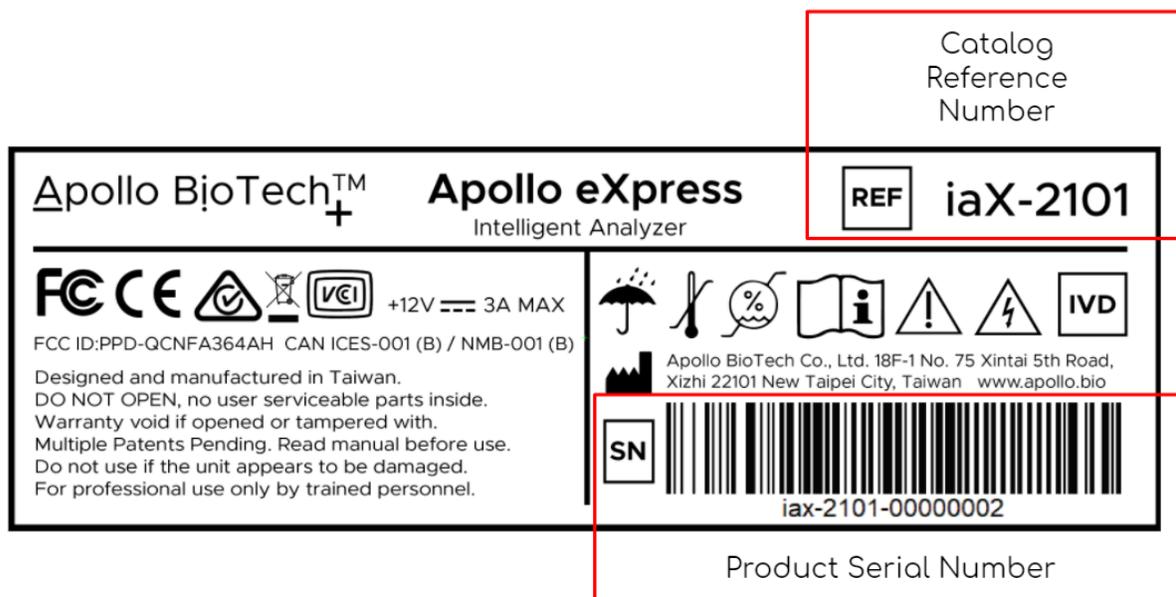
Please visit:

<https://apollo.bio/AdverseEvents>

Collect and use the Catalog Reference Number and the Product Serial number found on your device as shown below.

Product Label

Below shows the label and important fields. Use these fields in correspondence and reporting of any issues related to the product.



Technical Specifications

Regulatory compliance

The Apollo iaX is tested for regulatory compliance under the following specifications:

Specification	Standard
CE	EN 60601-1-2 (2015), IEC 60601-1-2 (2014-02) CISPR 11 (2015+A2: 2019), ICE/EN61000-3-2 (2020)/-3 (2013/A1:2017) IEC/EN61000-4-2 (2009)/-3 (2020)/-4 (2012)/-5 (2014+A1:2017)/-6 (2014)/ -8 (2010)/-11 (2020))
FCC	47 CFR PART 18 Part 18 § 18.307/18.305
VCCI	
Electrical Safety	ISO 14971
Testing Accreditation	FCC Registration No: TW1477, TW0020, TW1072 Industry Canada filed test laboratory reg no 20037 A2LA Accredited No: 2732.01 TAF Testing Laboratory #1477 ILAC MRA
FCC Report No	W6M22011-20420-P-18
CE Report No	W6M22011-20420-E-11

Branding and “RAPID”

The “assaya” logo, brand and the slogan “Universal Mass RAPID Testing” is a trademark of Apollo BioTech co., ltd.

The acronym “RAPID” when capitalized and used as an adjective or adverb is a term coined by the Apollo BioTech founder Clas Sivertsen, and is defined as follows: “Rapid Accurate Practical Inexpensive Diagnostics”.

Compute Node Specification

The internal PC of the iaX has the following technical details

Item	Specification
Form Factor	Pico-ITX
CPU	Intel [®] Atom [™] Processor SoC
CPU Frequency	Up to 2.4 GHz
Memory	Onboard DDR3L 4GB
BIOS	American Megatrends Inc. (AM/SPiI)
Motherboard Power	+12V Typ 13.2W
MTBF	110,000 hours (~12.5 years)

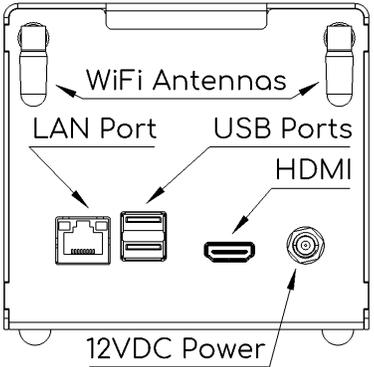
LED Camera and Lighting Board Specification

The iaX has a circuit board assembly consisting of a USB Camera and a USB controlled lighting board with the following technical details

	Item	Specification
Camera	Module	Alcor AJ9010B37
	Resolution	1280x720 (720p)
	Format	YUY2
	Interface	USB2.0 UVC Video Device Class
	Firmware	VER 002A72B8-R201125
	Lighting Board	CPU
LED Spectrum		IR, RGB, White, UVA, UVB, UVC

Product Overall Specification

The iaX top level product us specified as follows:

Item	Specification
Full Product Name	Apollo eXpress
Catalog Model Number	iaX-2101
Configuration:	 <p>The diagram shows the rear panel of the iaX-2101 device. It features two WiFi Antennas at the top. Below them are a LAN Port, two USB Ports, and an HDMI port. At the bottom, there is a 12VDC Power input.</p>
Operating System	Ubuntu 20.04 LTS
Typ. Total Avg. Power Consumption	15W
Power Supply Rating	+12VDC 3A (36W)
Weight (bare unit)	605g
Ideal Operating Temp	18-25 C
Max Ambient Operating Temp *)	35 C
MIn Ambient Operating Temp *)	5 C
USB	2x USB 2.0
CPU	Intel® Pentium® N4200
Memory	Onboard DDR3L 4GB
Storage	eMMC 32GB
LAN	Single Gigabit Ethernet
WiFi (RJ45)	Wireless.802.11 ac/a/b/g/n + BT 5.0.2T2R Enli QCNFA364A
Antennas	INVAX AN35 2.4GHz

*) Note: This temperature may not be compatible with some of the test kits

Product Registrations and Certifications

The iaX top level product us specified as follows:

Item	Specification
Taiwan FDA (TFDA)	MHW Medical Device Manufacturing No. 009155
USA FDA (US-FDA)	<p>Registration & Device Listing: APOLLO BIOTECH CO., LTD. 18F-1 No. 75 Xintai 5th Road Xizhi 22101 New Taipei City, TW 22101 Status: Active; Awaiting Assignment Of Registration Number Date Of Registration Status: 2021</p> <p>Owner/Operator: Apollo BioTech Co., Ltd. 18F-1 No. 75 Xintai 5th Road Xizhi 22101 New Taipei City, TW 22101 Owner/Operator Number: 10082148</p>
US Agent/importer:	<p>assaya LLC 300 Colonial Center Parkway STE 100N, Roswell, GA, 30076, USA Web: www.assaya.com Email: ae@apollo.bio</p>
GMP Certified Manufacturer:	<p>Amedifact Co., Ltd. No. 23, Wuquan Road, Wugu District, New Taipei City TAIWAN Web: www.amedifact.com</p>

Patents and Patents Pending

This product is covered under a number of patents. For an up-to-date list please visit:

www.apollo.bio/pat

Service and Contact Information

Please see the Apollo BioTech website for links to your nearest service provider:

<https://apollo.bio>

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Revisions

The below tables lists the revisions made for each version of this document.

2020 Dec 27 v1.0	Original Release. Revisions before 1.0 are considered drafts
2021 Jan 7 v1.1	Updated front page picture to reflect updated device branding changed from aia (apollo intelligent analyzer) to iaX-2101, where ia = intelligent analyzer and 2101 refers to the target 2 digit year code and month code of the product release.
2021 Jan 17 v1.2	<ul style="list-style-type: none"> - Added this revisions section - Changed page 24 from EU to EMEA as territory for Apollo BioTech GmbH
2021 Jan 19 v1.3	Added the assaya brand logo and RAPID
2021 July 2 v1.4	Added Certifications and Patents link