INVITEK
diagnostics

Instructions for Use
InviDx® System



Language: EN

RUO

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Important Notes

Thank you for choosing the **InviDx® System** from Invitek Diagnostics.

The InviDx® System is an automated platform intended to perform nucleic acid amplification, colorimetric-based detection, and software-assisted analysis when used with compatible test kits developed and validated for the platform. Each test kit provides assay-specific reagents and instructions, while the InviDx® System performs nucleic acid amplification, data aquisition, and automated result interpretation.

The InviDx® System is for **Research Use Only.** It is not intended for use in diagnostic procedures or for the diagnosis, screening, prognosis, monitoing, treatment, or management of any disease of medical condition.

All versions of the instructions for use can be found on our website for download or can be requested from us at www.invitek.com

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1. General Information

These Instructions for Use (IFU) describe the intended operation of the InviDx® System, including the InviDx® Instrument and the InviDx® Hub Application.

2. Intended Purpose

The InviDx® System is a qualitative, automated research-use platform intended to perform nucleic acid amplification, colorimetric-based detection, data acquisition, and software-assisted analysis when used with compatible test kits developed and validated for the platform. Each test kit provides assay-specific reagents and instructions, while the InviDx® System performs nucleic acid amplification, detection, and automated result interpretation.

The InviDx® System consists of an instrument that performs nucleic acid amplification and signal detection, and the InviDx® Hub, a web-based application that processes and displays data according to the selected assay protocol.

The InviDx® System is intended for use by trained research and laboratory personell, without specialized expertise in molecular biology. Data and results generated by the system are intended solely for research purposes. For Research Use Only.

The InviDx® System is suitable for near-sample and decentralized testing environments, provided that the environmental, operational, and safety requirements specified in these Instructions for Use are met.

3. Indications

- The InviDx® System is intended for laboratory research applications involving nucleic acid amplification and colorimetric detection using compatible InviScreen® test kits.
- The system may be used to detect specific nucleic acid target sequences using Loop-mediated Isothermal Amplification (LAMP) technology, where supported by the selected research assay and protocol.
- All testing and resulting data are for research purposes only and must not be used for diagnostic or clinical decision-making purposes.
- Use only the cables supplied with the system.
- Do not move the instrument while a run is in progress.

4. Intended User

The InviDx® System is intended for use by trained research and laboratory personnel. Specialized expertise in molecular biology is not required.

5. General Principle and Process Overview

The InviDx® System is a portable, bench-top, automated research-use platform designed to perform nucleic acid amplification, colorimetric detection, and software-assisted analysis when used with compatible research-use test kits developed for the platform. The system supports research testing based on assay-specific reagents, parameters, and instructions supplied with each compatible research-use test kit.

Pre-prepared reaction strips are loaded into the instrument. A built-in sensor ensures that the reaction starts only after the lid has been closed. The system performs isothermal amplification at the assay-specific temperature and time (typically 30–45 minutes, depending on the test kit),

monitors the reaction through periodic image capture and transfers data to the InviDx® Hub web app for analysis according to the selected protocol.

The InviDx® System processes one reaction strip containing 12 wells per run. It integrates automatic test process control and self-diagnostic functions, supports Wi-Fi and Ethernet connectivity, and includes LED indicators for operational status.

The InviDx® Hub Application web app is identified by a unique version number. The current version is displayed within the application.

6. InviDx® System

The InviDx® System consists of an instrument and a web application that, when used with compatible research-use assay kits, performs LAMP-based nucleic acid amplification, reaction monitoring, data analysis, and generation of research-use analytical outputs.

6.1 InviDx® System Components

The InviDx® System consists of:
- InviDx® Instrument
- InviDx® Hub Web App
- Compatible Test Kits validated for use with the platform

SYSTEM ELEMENT	FUNCTION
InviDx® Instrument	Performs isothermal amplification, image capture, device self-checks and data transfer.
InviDx® Hub Web App	Supports user access, instrument selection, run setup, data analysis, qualitative result interpretation, run history, data export and audit trail.
Compatible Test Kit	Provides assay-specific reagents, controls, specimen requirements, protocol parameters, performance characteristics and target claims.

The InviDx® instrument includes the hardware and embedded software required to perform the assay run according to the selected compatible test kit protocol. The instrument includes a heating block, temperature controller, illumination, optical image capture, status indicators, power control and network communication functionality.

During operation, the embedded software controls the assay-specific isothermal temperature, monitors device readiness and operating conditions, supports internal self-checks, detects lid closure and strip insertion, captures reaction images and transfers run data securely to the InviDx® Hub.

The InviDx® Hub web app is used to manage user access, select instruments and protocols, initiate and monitor runs, process reaction data, generate qualitative results, maintain traceability, and export reports.

The user must ensure that the correct compatible test kit protocol is selected, the reaction strip is correctly inserted, the lid remains closed during operation, and network connectivity is available for run initiation, result processing and reporting. Access to the InviDx® Hub is controlled by authorized user accounts. System activities are logged to support traceability, troubleshooting and audit requirements.

The InviDx® Hub uses network communication for data processing, result reporting, and storage of run records.

6.2 Network Connection Requirements

Before connecting the InviDx® Instrument to the InviDx® Hub, ensure that the network meets the following requirements:

- For connection via Ethernet, DHCP must be enabled on the network to allow the InviDx® Instrument to obtain the required network configuration automatically.
- The network must permit NTP (Network Time Protocol) communication via port 123 for time synchronization. Access to the following NTP services must be permitted, as applicable:
  - time.windows.com
  - microsoft.com
  - time.cloudflare.com
  - time.google.com
  - apple.com
  - time.aws.com
  - timeapi.io
- The network must permit communication with the Microsoft Azure IoT Hub Device Provisioning Service (DPS) at global.azure-devices-provisioning.net via port 443 (HTTPS) and/or port 5671 (AMQP over TCP).
- The network must permit access to the InviDx® Hub at **apps.invitek.com** via HTTPS (port 443).

If the network is managed by an IT administrator or uses firewall restrictions, ensure that the required addresses, ports, and protocols are permitted before attempting to connect the instrument.

6.3 Calibrators and Controls

The InviDx® System includes internal process controls and diagnostic checks that verify proper instrument operation throughout the test run.

6.4 Materials Provided

- InviDx® Instrument
- Power supply unit
- Power plug unit (EU, US or UK plug)

6.5 Materials Required (not provided)

Compatible InviScreen® test kits supplied by Invitek Diagnostics.

6.6 Storage, Handling and Cleaning of InviDx® System

Keep the InviDx® hardware dry and do not expose it to water.
Operate the system at room temperature, with a suggested range of 15 °C to 30 °C and relative humidity between 30 % and 75 % (non-condensing). Refrigeration or freezing is not permitted. During operation, the device must be positioned away from direct air currents to ensure proper performance. During operation and running, the device should not be moved. For long-term storage, the system should remain in its original packaging at room temperature.
The InviDx® System requires minimal maintenance for proper operation. Prolonged use will, however, require occasional cleaning:

- Never run a reaction strip with an open, loose, punctured or damaged cap.
- Do not use ethanol at the outer parts of the device, as it may cause the loss of color's intensity.
- Keep the reaction chamber clean. In case of suspected contamination, contact Invitek Diagnostics.

7. Sample Collection, Handling, and Preparation

Requirements for sample collection, transport, storage, and preparation are provided in the Instructions for Use of the compatible InviScreen® test kit. Users must follow the assay-specific Instructions for Use and sample handling requirements for the selected test kit.

8. InviDx® Procedure

The InviDx® System automates assay processing, including temperature control, reaction monitoring, and data transfer required for result generation. Operation of the InviDx® System is divided into the following steps:

8.1 Unpackage and Installation

- Upon receipt of the InviDx® instrument from Invitek Diagnostics, the packaging should be inspected for any visible damage. Any detected damage must be reported immediately to Invitek Diagnostics Technical Support.
- Unpack all components and remove the InviDx® instrument, the power supply unit, and the power plug unit from the packaging.
- Verify that all items are present and inspect them for visible damage. If any damage is identified, the instrument must not be operated. Contact Invitek Diagnostics Technical Support.
- The InviDx® system must be placed on a level, dry, and stable surface near a wall socket. Refer to the device label and supplied power adapter for electrical requirements.

8.2 InviDx® Hub Registration

- The InviDx® web app is a web-based platform and does not require installation from an application store.
- To access the web app, open a supported web browser on a compatible device.
- Enter **apps.invitek.com** in the browser address bar.
- The InviDx® Hub login page is displayed.
- Select the preferred language, if applicable. The language settings can be changed from the login page or within the application settings after login.
- Invitek Diagnostics provides the primary client organization with a Super User (Organization Admin) account.

- The Super User (Organization Admin) receives an email containing instructions to complete a mandatory password reset. Authentication is available only after the password reset has been completed.
- Following successful authentication, access to the system dashboard is granted.
- The Super User (Organization Admin) has administrative privileges for the organization's account.
- Additional user accounts may be created through the ***Users*** section of the web app.
- Newly created users receive an email with instructions to establish their passwords.
- Authorized users may log in using their assigned credentials.
- User access and available actions are determined by the roles and permissions assigned to each user.
- All user activities are logged within the system to ensure traceability.

8.3 Powering On and Connecting the InviDx® Instrument

- Verify that the InviDx® Instrument is switched OFF before connecting the power supply.
- Connect the power supply to the device and to a suitable electrical outlet.
- Switch the instrument ON.
- Allow the system to complete the startup and initialization process (approximately 2 minutes). During first-time startup, initialization may require up to 5 minutes.
- Using a compatible computer or tablet connected to the same network as the instrument, open a supported web browser.
- Enter **apps.invitek.com** in the browser address bar.
- Authenticate using the registered email address and password.
- Following successful authentication, the main dashboard is displayed.
- Select ***New Run***.
- All instruments associated with the organization and available on the network are displayed automatically.
  - The status of each instrument is shown as Online, Offline, Warning, or Unknown/Not Registered.
- Select the instrument on which the run will be performed.

8.4 Preparing the Samples

- Samples must be prepared strictly in accordance with the Instructions for Use (IFU) of the respective InviScreen® test kit being used.
- Upon completion of sample preparation, the 12-well reaction strip is ready for loading into the instrument.
- The reaction strip must be placed in the designated position within the device, ensuring correct orientation and proper seating in the holder prior to initiating the run.

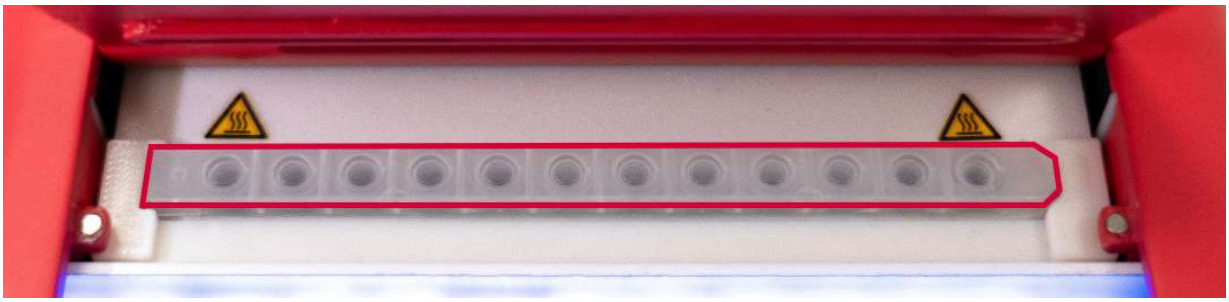

Fig. 1: A 12-well reaction strip inserted into the InviDx® instrument. Ensure the strip is correctly oriented, with the square end on the left and the rounded end on the right.

8.5 Starting a Run on InviDx®

- Navigate to ***New Run*** within the web app.
- Enter the required run information, including:
  - Run name;
  - Sample name(s);
  - Instrument selection;
  - Test protocol selection;
- Review the entered information and click on the ***Run Sample*** icon to start the run.
- Upon successful connection to the selected instrument, the system automatically performs a hardware diagnostic check.
- If the diagnostic check is completed successfully, the instrument automatically initiates the warm-up phase.
- The heating module raises the temperature to the target value defined by the selected protocol.
- The current temperature and system status are displayed in the web app interface.
- When the target temperature has been reached and stabilized, the system indicates that the instrument is ready for sample loading.
- Open the instrument lid and insert the prepared reacion strip into the designated holder. Ensure correct orientation and proper seating of the strip.
- Close the intrument lid securely.
- The system automatically detects lid closure.
- Once strip placement and lid closure have been verified, the run starts automatically.
- The run proceeds according to the parameters specified in the selected protocol.

8.6 Stopping a Run

- To stop a run before completion, navigate to the ***Active Runs*** page and select ***Cancel Run***.
- A confirmation dialog is displayed.
- Confirm the action to terminate the run.
- Stopped runs remain available in the ***Run History*** section of the application.
- To access completed, terminated, or archived runs, navigate to ***Run History***.

8.7 Run Completion

- An internet connection is required to synchronize and archive completed run data in the InviDx® Hub.
- Temporary loss of internet connectivity during a run does not interrupt run execution. However, internet connectivity must be restored after run completion to ensure that the run data are synchronized and archived in ***Run History***.
- Upon successful completion, the run is removed from ***Active Runs*** and becomes available in ***Run History***.
- After run completion has been confirmed, open the instrument lid.
- Carefully remove the reaction strip from the designated holder, taking care to avoid spills or contamination.

CAUTION: Do not open reaction tubes following analysis. Opening tubes may result in amplicon contamination of the instrument and surrounding environment.

8.8 LED Indications

The operational status is indicated by the LED signaling patterns described below.

OPERATIONAL STATE	DESCRIPTION	LED SIGNALLING (Color/Blink Speed)
OFF	Instrument powered off	LEDs off
BOOT	Instrument startup, initialization, and self-diagnostics in progress.	Blue, slow blinking
IDLE	Instrument ready and awaiting commands from InviDx® Hub.	Depends on connection status; see Table below.
WARMUP	Heating block warming to the target assay temperature.	Yellow, slow blinking
STRIP INSERTION	Target temperature reached. Awaiting strip insertion, lid closure, and run start command from InviDx® Hub.	Yellow, fast blinking
RUNNING	Assay amplification and image acquisition in progress.	Green, slow blinking
FINISHING	Run completed. Data synchronization and transfer in progress. If this state persists for an extended period, the instrument may have lost network connectivity.	Green, steady
ERROR	Critical instrument error detected. Run execution is not possible until the error condition is resolved.	Red, steady

Following completion of the boot process, the instrument continuously monitors its connectivity status to InviDx® Hub. The connectivity status is indicated by one of the following three states:

OPERATIONAL STATE	DESCRIPTION	LED SIGNALLING (Color/Blink Speed)
DISCONNECTED	No network connection available. The instrument is awaiting connection via Ethernet or Wi-Fi. The Wi-Fi hotspot and local web interface are available for network configuration.	Orange, slow blinking
CONNECTING	Establishing a connection to InviDx® Hub.	Blue, slow blinking
CONNECTED	Connected to InviDx® Hub and ready for normal operation	Blue, steady

8.9 Data Processing

The InviDx® System captures images of the reaction strip throughout the run. The InviDx® Hub web app analyses the acquired data using assay-specific algorithms and generates qualitative test results according to the selected protocol.

8.10 Run History and Results Interpretation

- The ***Run History*** section displays runs available to the user based on assigned permissions.
- Runs may be filtered by Run Name, Date, Time, Instrument, Protocol, and Status.
- To view detailed information for a run, select the ***View*** icon in the Actions column.
- The ***Run Details*** page is displayed and contains the following tabs:

Results Tab
Displays the following information:
- Run Name;
- Sample Name;
- Instrument;
- Protocol;
- Run Status (**Complete**, **Canceled**, **Invalid**, or **Error**);
- Control Results:
  - Positive and negative controls are reported as **Passed** or **Failed**.
  - If any control fails, the run is automatically classified as **Invalid**.
- Target Results:
  - Results for each assay target are displayed as **Positive** or **Negative**.

Visualization Tab
Displays color index amplification curves generated during the run.

Run Log Tab
Displays run-specific metadata and an audit trail of events recorded during run execution.

Export Tab
Provides the option to generate a PDF report for the selected run. To export the report, select ***Export to PDF***. The generated PDF may be saved locally for documentation, archiving, or sharing purposes.

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The table below defines the user action for the main result and run-status categories.

DISPLAYED STATUS/ RESULT	MEANING	USABLE?	REQUIRED USER ACTION
Positive target result	Target-specific amplification signal met the assay-specific calling criteria and controls passed.	Yes, if run is completed and all required controls pass.	Analyse the output in accordance with the applicable protocol.
Negative target result	Target-specific amplification signal did not meet the assay-specific positive calling criteria and controls passed.	Yes, if run is completed and all required controls pass.	Analyse according to the applicable protocol.
Control Passed	The applicable assay control met the acceptance criteria defined for the selected test protocol.	Yes.	Review all controls and target results before using results.
Control Failed	One or more applicable controls did not meet the acceptance criteria.	No.	Do not use results. Repeat the test according to the test kit IFU and investigate the cause.
Invalid	The run or sample result is not valid due to control failure, instrument/software error, unsafe operation, or failure to meet acceptance criteria.	No.	Do not use results. Repeat if allowed by the test kit IFU; contact Technical Support if repeated.
Error	A system, device, software, network, thermal, optical or sensor error occurred.	No, unless a completed valid result is already available and the error is confirmed not to affect it.	Follow troubleshooting instructions. Contact Technical Support if unresolved.
Cancelled / Stopped	The run was stopped before scheduled completion.	No.	Do not use results. Repeat with a new prepared reaction strip if required.
Connectivity pending / Finishing	The run has ended but final final data transfer to the InviDx® Hub is pending.	No until final result is available in the InviDx® Hub.	Restore connectivity. Do not use results until the run is completed, controls have passed and results are available in Run History.

9. Quality Control

9.1 Quality Control Procedures

Quality control for each test run is performed using the controls included in the compatible test kit.
The InviDx® System also performs automated instrument checks before and during run execution, including readiness and operating-condition verification.
A run is considered valid only when all of the following conditions are met:

- the control acceptance criteria defined for the compatible test kit are fullfiled;
- no run-invalidating instrument or software errors are detected;
- the run is completed successfully and the results are available in the InviDx® Hub.

If any control fails or if the system reports an invalid or error status, the results must not be used. Refer to the IFU of the compatible test kit, the previous table, and Section 10 (Troubleshooting) of this IFU for further guidance.

9.2 Metrological Traceability

Information regarding metrological traceability and control materials is provided in the IFU and technical documentation of the compatible test kit, where applicable. The InviDx® System does not require and does not provide user-adjustable calibration functions. Users must not modify instrument calibration settings, firmware, software, assay protocols, or result interpretation thresholds.

10. Troubleshooting

The InviDx® System continuously monitors instrument status, operating conditions, and connectivity during operation. If a problem is detected, an error message, warning, or status indication may be displayed in the InviDx® Hub web app.
If the instrument indicates an Error state (steady red LED), restart the instrument and verify that the error condition has been resolved. If the Error state persists after restart, discontinue use of the instrument and contact Invitek Diagnostics Technical Support.
If a problem cannot be resolved using the guidance below, discontinue use of the system and contact Invitek Diagnostics Technical Support.

10.1 Instrument Startup and Connectivity

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Instrument does not power on	Power supply not connected, power interruption, faulty electrical outlet.	Verify power connections and confirm that the electrical outlet is functional. Use only the supplied power adapter.
Instrument fails to complete startup	Internal system fault detected during initialization.	Restart the instrument. If the problem persists, contact Technical Support.
Instrument is not visible or shows Offline status in InviDx® Hub	Instrument not connected to network.	Verify Ethernet or Wi-Fi connectivity. Ensure the instrument and user device are connected to the appropriate network.
Instrument cannot connect to InviDx® Hub	Internet connection unavailable or cloud service temporarily unreachable.	Verify internet access and try again. Contact Technical Support if the problem persists.
Incorrect date or time displayed	Time synchronization failure.	Verify network connectivity and restart the instrument.

10.2 Run Setup and Configuration

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Unable to create a new run	Duplicate run identifier.	Enter a unique run identifier and create the run again.
Instrument cannot be selected	Instrument currently busy or unavailable.	Confirm that the instrument is available. Wait for the current activity to finish or select another suitable instrument.
Run cannot start	Required information not entered.	Complete all mandatory fields and verify the run details before starting the run.
Run cannot start	Storage or system resource limitation.	Check available storage and system resources. Free up capacity or close unnecessary applications, then restart the run. If the issue persists, contact Technical Support.

10.3 Sample Loading and Run Initiation

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Reaction strip not detected	Strip incorrectly inserted, missing, or improperly positioned	Remove and reinsert the reaction strip according to the Instructions for Use.
Lid open warning displayed	Lid not fully closed	Close the lid securely and confirm that the warning is cleared.
Run does not start after strip insertion	Lid not detected as closed or strip not properly seated	Verify strip placement and securely close the lid.
Run aborted immediately after start	System detected an operational fault	Repeat the run with a new prepared reaction strip. If the error recurs, contact Technical Support.

10.4 Temperature and Instrument Errors

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Instrument unable to reach operating temperature	Heating system fault or unsuitable operating environment	Verify environmental conditions and restart the instrument. Contact Technical Support if the problem persists.
Temperature warning displayed	Temperature instability detected	Allow the instrument to stabilize and repeat the run if required.
Thermal error displayed	Instrument operating outside specified conditions	Verify ambient temperature and airflow conditions. Restart the instrument after the error condition is resolved.
Sensor error displayed	Internal sensor malfunction	Restart the instrument. Contact Technical Support if the error persists.
General instrument error	Internal hardware fault	Do not report results. Contact Technical Support.

10.5 Optical Detection and Image Analysis

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Camera initialization error	Optical system fault	Restart the instrument. Contact Technical Support if the problem persists.
Image acquisition error	Camera or imaging system malfunction	Repeat the run if possible. Contact Technical Support if the issue recurs.
Image quality warning	Reaction strip image unsuitable for analysis	Verify correct strip placement and instrument cleanliness. Repeat the test if required.
Run invalid due to image quality	Optical analysis could not be completed	Prepare a new reaction strip and repeat the test according to the compatible test kit IFU.

10.6 Connectivity Loss During a Run

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Network connection lost during run	Temporary network interruption	The run will continue. Restore network connectivity as soon as possible.
Run remains in Finishing status	Final data transfer to InviDx® Hub is pending	Re-establish internet connectivity and allow synchronization to complete.
Results not visible in Run History	Data upload not completed	Verify connectivity and wait until synchronization is completed.

CAUTION: Temporary loss of internet connectivity during amplification does not interrupt the test run.

Results become available only after successful synchronization with the InviDx® Hub.

10.7 Result and Quality Control Issues

STATUS	MEANING	USER ACTION
Control Failed	One or more assay control criteria not met	Do not report results. Repeat testing according to the compatible test kit IFU.
Invalid	Acceptance criteria not met	Do not report results. Repeat testing if permitted.
Error	Instrument, software, or operational error occurred	Do not report results. Follow troubleshooting instructions and repeat testing if appropriate.
Cancelled	Run manually stopped before completion	Results must not be reported. Repeat testing with a new prepared reaction strip if required.

10.8 When to Contact Technical Support

Contact Invitek Diagnostics Technical Support if:

- the instrument repeatedly fails startup diagnostics;
- network connectivity issues cannot be resolved;
- temperature, sensor, or optical errors recur;
- multiple runs become invalid without an identifiable cause;
- the instrument displays a persistent Error status;
- results cannot be synchronized to the InviDx® Hub after connectivity is restored;
- any unexpected instrument behavior occurs.

11. Warnings And Precautions

The general warnings are detailed bellow:

- For Research Use Only.
- The InviDx® System is intended for use by trained research and laboratory personnel in accordance with the instructions provided.
- Do not use the system with assay kits, reagents, or protocols that have not been approved by Invitek Diagnostics for use with the applicable InviDx®. The use of non-validated reagents or components may result in unreliable data.
- Do not open the system during operation: opening the device while a test is running may lead to temperature fluctuations, interruption of image acquisition, and invalid results.
- Wear protective clothing, including laboratory coat and disposable gloves while handling assay and samples. Wash hands thoroughly after handling specimens. Disinfect the area where the analysis took place.
- The system transmits test data to a cloud-based web app for result interpretation. Ensure a stable internet connection for remote data processing and report generation.
- Used test consumables, including reaction strips, should be disposed of according to biohazard waste disposal guidelines to prevent environmental contamination and health risks.

12. Installation, calibration and maintenance

The InviDx® System contains no user-serviceable or user-adjustable calibration functions.

Users should perform routine visual checks before use:

- the instrument is clean and dry;
- the housing is free from visible damage;
- the lid closes properly;
- the power supply and cables are undamaged;
- the instrument connects successfully to the InviDx® Hub;
- no unresolved warning or error status is displayed.

Clean external instrument surfaces using the cleaning procedures specified by Invitek Diagnostics.
Do not attempt to modify, repair, or service the instrument. Contact Invitek Diagnostics Technical Support if maintenance or repair is required.
Use only approved software versions provided by Invitek Diagnostics.
Software updates may be communicated through the InviDx® Hub or by Invitek Diagnostics. Review any updated Instructions for Use or release information provided with software updates.
Report unexpected software behaviour, cybersecurity concerns, persistent warnings, or instrument faults to Technical Support.

13. Software

The InviDx® Hub is a web-based application used for run setup, run monitoring, result processing, result review, report export, and storage of run records.

Access to the InviDx® Hub is restricted to authorized users and requires a supported web browser and network connection.

The InviDx® Instrument includes embedded firmware that controls instrument operation, including temperature control, lid detection, image capture, device self-checks, and transfer of run data to the InviDx® Hub.

Software and Firmware Identification

SOFTWARE AND FIRMWARE IDENTIFICATION	LOCATION
InviDx® Hub web app version	Displayed within the application
Instrument firmware version	Displayed within the application
Assay protocol version	Displayed during run configuration
Report template/version	Displayed in exported reports

Minimum User Requirements

REQUIREMENT	MINIMUM USER-FACING REQUIREMENT
Operating System	Any operating system supporting modern web browsers
Browser	None
Memory	8 GB RAM or above
Network	Stable internet/network connection
Storage	No local storage needed other than browser usage
Software Dependency	None

Access to the InviDx® Hub is controlled through user accounts and permissions. User activities are recorded within the system to support traceability and audit requirements.

Use only software and firmware versions approved by Invitek Diagnostics. Software updates may be communicated through the InviDx® Hub or by Invitek Diagnostics. Users should review any updated Instructions for Use or release information provided with software updates.

Report unexpected software behavior, persistent application errors, or suspected cybersecurity incidents to Invitek Diagnostics Technical Support.

14. Limitations

- The InviDx® System is for Research Use Only. Not for use in diagnostic procedures.
- The system has not been established for diagnosis, screening, prognosis, patient monitoring, treatment selection, or other clinical decision-making.
- The performance of the InviDx® System is dependent on the characteristics and performance of the associated test kit. Limitations specific to individual assays must be considered in conjunction with this IFU.
- The system performs qualitative detection and automated interpretation; results are dependent on proper operation of both hardware and software components.
- Incorrect, invalid, or indeterminate results may occur due to instrument or software malfunction, including failures in temperature control, optical detection, sensors, internal diagnostics, or data analysis algorithms.

15. Symbols

	Research Use Only
	Manufacturer
	Lot number
	Catalogue number
	Consult operating instructions
	Temperature limitation

16. Technical and customer service

For additional information about the use of InviDx® System, please contact:

Technical support:
techsupport@invitek.com

GERMANY

Haynauer Str. 60, 12249 Berlin, Germany

+49 30 21927068

PORTUGAL

Zona Industrial de Tondela, ZIM II, Lote 6, 3460-070 Tondela, Portugal

+351 232 817 817

17. Legal notice

Any product complaint, unexpected instrument or software behaviour, safety concern, or other event associated with use of the InviDx® System should be reported to the Invitek Diagnostics Technical Support at techsupport@invitek.com.
Where applicable, users should comply with any institutional or local reporting requirements relevant to their research activities.

18. Document history

Revision	Date	Description
DE 705.01_EN	2026-09-06	New document

invitek.com

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diagnostics

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