Applied BioCode

Barcoded Magnetic Beads | Highly Multiplex Assays

BioCode® STI + Resistance Panel (RUO) Package Insert

Catalog # 63-S0002

For Research Use Only.
Not for use in diagnostic procedures.

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INTRODUCTION

The BioCode® STI + Resistance Panel (RUO) [STI+ Panel] is a multiplex nucleic acid amplification test intended for research use only. It is specially designed for utilization with the BioCode® MDx-3000 Instrument. This qualitative panel can simultaneously detect and identify nucleic acids from the bacterial and protozoan pathogens, as detailed in Table 1. Additionally, it can identify macrolide-resistant and fluoroquinolone-resistant single nucleotide polymorphism (SNP) mutations, as outlined in Table 2. The test employs a single multiplex reaction allowing for the detection and differentiation of all targeted pathogens, antimicrobial resistance for NG and MG, and the DNA extraction control for each sample.

Table 1. Pathogens detected by the STI+ Panel.

STI+ Resistance Panel Pathogens and their Gene Targets		
Pathogen Classification	**Pathogen Targets**	**Gene Targets**
Gram (-) Bacteria	*Chlamydia trachomatis* (CT)	*pmpH* gene
	Neisseria gonorrhoeae (NG)	*porA* pseudogene
	Mycoplasma genitalium (MG)	*MgpB* gene, *parC* gene
Protozoan	*Trichomonas vaginalis* (TV)	*16S rRNA* gene, ITS region
T4 Phage (DNA-IC; Extraction Control)		

Table 2. Organisms & associated antimicrobial drug resistance mutations included in the STI+ Panel.

Antibiotic Resistance Mutations detected by STI+ Resistance Panel (RUO)			
Antimicrobial Drug Class	**Organism**	**Gene**	**Mutation**
Fluoroquinolones	*Mycoplasma genitalium*	*parC*	G248T (S83I)
	Neisseria gonorrhoeae	*gyrA*	C271 (S91 WT*)
			C271T (S91F)
Macrolides	*Mycoplasma genitalium*	*23S rRNA*	A2058C
			A2058G
			A2058T
			A2059C
			A2059G
			A2059T

*Wildtype

SUMMARY AND EXPLANATION OF THE TEST

The STI+ Panel is a multiplex nucleic acid amplification test designed to qualitatively detect deoxyribonucleic acids (DNA) from CT, NG, TV, and MG, while assessing specific drug resistance mutation(s) that lead to macrolide (MclR) and fluoroquinolone resistance (FlqR). Targeting two distinct genome regions for each pathogen, detailed in Table 1, enhances the precision of detection. Although the same gene is utilized for detection in CT and NG, different regions within the gene were used to design primers and probes. Macrolides and fluoroquinolones, commonly prescribed antibiotics for sexually transmitted infections (STIs) like NG and MG, can be rendered ineffective due to resistance mutations. In NG, fluoroquinolone resistance often stems from the S91F mutation in its *gyraseA* gene[1-5] while in MG, the S83I mutation in its *parC* gene [6-7]is implicated. Macrolide resistance can arise from

specific mutations in the 23S ribosomal DNA [6-7] in the MG genome. The STI+ Panel is designed for use with the BioCode® MDx-3000 automated system, providing test results in approximately 4 hours post-DNA extraction. It is designed for research purposes only and is not intended for use in diagnostic procedures.

PRINCIPLE OF PROCEDURE

The BioCode® MDx-3000 is an automated system that seamlessly integrates PCR amplification, target capture, signal generation, and optical detection of nucleic acids. Together with the STI+ Panel, this system enables the detection of any of the 4 STI pathogens alongside specific drug resistance mutation(s) linked to MG macrolide resistance (MclR), as well as fluoroquinolone resistance (FlqR) in MG or NG.

Overview of a BioCode® MDx-3000 Run

1. **Multiplex PCR** –Extracted nucleic acid is added to a freshly prepared multiplex PCR reaction mix to amplify any of the 4 STI targets and targets associated with antimicrobial resistance (AMR) present in the sample. In each primer pair, one primer is biotinylated at the 5'-end to produce labeled PCR products for subsequent detection.
2. **Dispensing BMB-Probe Mix** – As PCR amplification nears completion, the instrument's robotic head dispenses BMB-Probe Mix into the assigned reaction wells of the capture plate using disposable pipette tips.
3. **PCR Product Transfer** – Following the completion of PCR amplification, the robotic head punctures the foil seal using disposable pipette tips to acquire the PCR amplicons and transfer them into the appropriate wells of the capture plate.
4. **Target Capture** – Biotin-labeled PCR amplicons are captured at a specific temperature by target-specific probes linked to designated Barcoded Magnetic Beads (BMBs). Throughout this process, the BMBs remain suspended through gentle agitation. To differentiate captured targets, each pathogen and the internal control is assigned a unique BMB pattern.
5. **Signal Generation** – Following the removal of both unbound PCR amplicons and primers via washing, the robot dispenses a streptavidin-phycoerythrin (SA-PE) conjugate into the reaction. The strong affinity between biotin and SA-PE ensures that PCR amplicons captured with the biotin moiety are labeled with phycoerythrin in close proximity to the BMBs.
6. **Optical Detection** – Optical detection is conducted for each reaction well of the optically clear, 96-well flat-bottom microtiter capture plate. Following the removal of unbound SA-PE conjugates through washing, excitation of the fluorophore at the designated wavelength elicits a fluorescence signal from BMBs tagged with SA-PE conjugates. Each reaction well is imaged at a specific emission wavelength for fluorescent signal and under bright field for identifying the barcode patterns (decoding).
7. **Software Analysis** – The BioCode® MDx-3000 Software controls the operation of the instrument, collects, and analyzes data, and automatically generates interpretation for test reports at the end of the run. Fluorescent signals from BMBs with the same barcode are sorted and calculated to generate median fluorescence intensity (MFI) for each analyte. For the STI+ Panel, the presence or absence of an STI pathogen or AMR target can be determined by Assay Specific Mode RUO STI-R protocol provided by ABC as a fixed protocol. The software also analyzes the results of optional external and internal controls to validate the run and individual specimen results.

MATERIALS REQUIRED

Materials Provided with Each Kit

Table 3. Reagents provided in the STI+ Panel Assay Kit – enough for 96 tests.

Component Name	Part No.	Contents	Storage
BioCode® Master Mix A	14-M0001	500 µL x 2	Store at -20°C before use. After thaw, store at 4°C for up to 30 days.
BioCode® STI + Res. Panel (RUO) Primer Mix	24-S0017	500 µL x 2	Store at -20°C before use. After thaw, store at 4°C for up to 30 days.
BioCode® DNA-IC	23-D0001	500 µL x 2	Store at -20°C before use. After thaw, store at 4°C for up to 30 days.
BioCode® STI + Res. Panel (RUO) BMB-Probe Mix	23-S0016	6000 µL x 1	Store at -20°C before use. After thaw, vortex for 30 sec, store at 4°C up to 90 days.

Materials Required but Not Provided with Each Kit

Table 4. General Reagents required for the BioCode® MDx-3000

Component Name	Part No.	Contents	Storage
BioCode® SA-PE Mix	63-S0001	450 µL x 8	Single use; protect from light; store at 4°C. **Do Not Freeze.**
BioCode® Buffer A	44-B0003	1 L x 1	Store at room temperature.

Table 5. BioCode® MDx-3000 consumables

Reagent	Source/Part No.	Quantity
Reagent reservoirs	Applied BioCode 01-R0005 or INTEGRA 4332	50 each x 4
Waste bin and lid	Applied BioCode 01-W0104 and 01-W0105	25 each
20 µL Pipette tips	Applied BioCode 01-P0006 or Beckman 717256	10 x 96 tips
250 µL Pipette tips	Applied BioCode 01-P0007 or Beckman 717252	10 x 96 tips
Bio-Rad 96-well hard-shell plate 0.1 mL	Applied BioCode 01-P0011 or Bio-Rad HSL9601	25 PCR plates
PCR adhesive foil	Applied BioCode 01-P0012 or Thermo Fisher Scientific AB-0626 or Eppendorf 0030127790	100 foils
Microtiter plate	Applied BioCode 01-P0009 or Greiner bio-one 655101	10 plates or 10 plates x 10 bags
Microtiter plate lid	Applied BioCode 01-P0010 or Nunc 5500	50 lids or 100 lids

Additional Equipment, Consumables and Reagents Required (but Not Provided)

- Negative Control matrix (e.g. 1X PBS, RNase free water)
- No Template Control matrix (e.g. 1X PBS, RNase free water)
- Positive Control
- Nucleic acid extraction system (e.g., MagNA Pure 96 [Roche], EMAG® [bioMérieux])
- BioCode® MDx-3000
- Vortex
- Mini Centrifuge and plate centrifuge
- Pipettes – single, multi-channel and/or repeater with accuracy range between 1-10 µL, 10-200 µL, and 100-1000 µL
- Sterile, RNase/DNase-free disposable aerosol-barrier micro pipettor tips
- 1.5 mL polypropylene micro centrifuge tubes and racks (RNase/DNase free recommended)
- Cooler racks for 1.5 mL tubes and 0.1 mL 96 well plate
- Biosafety cabinet (laminar flow hood) for extractions
- Freezer (manual defrost) at -10 to -30°C
- Freezer (manual defrost) at -60 to -90°C
- Refrigerator at 2 to 8°C

WARNINGS AND PRECAUTIONS

General Precautions

1. For Research Use Only. Not for use in diagnostic procedures.
2. The STI+ Panel Assay is to be used with the BioCode® MDx-3000.
3. Contamination may occur if the carryover of samples is not adequately controlled during sample handling and processing or from the environment.

Laboratory Precautions

1. The STI+ Panel Assay should be performed in clearly defined work areas moving in one direction from pre-amplification areas to the amplification/detection area to reduce potential for contamination.
   a. Begin with reagent preparation before moving to amplification/detection.
   b. Use dedicated equipment and supplies for each area (including personal protective equipment, such as lab coats and disposable gloves).
   c. Clean work areas with 10% bleach or similar disinfectant followed by 70% ethanol before and after assay preparation.
2. A negative control is required for each run, when using the Assay Specific Mode. If different lots of a kit are assayed at the same time, a negative control is required for each kit lot.
3. Do not use reagents past the expiration date. It is not recommended to mix reagents or interchange kit components from different kit lots. Kit configurations are identified on the kit outer box.
4. Assay setup should be performed at room temperature.

Safety Precautions

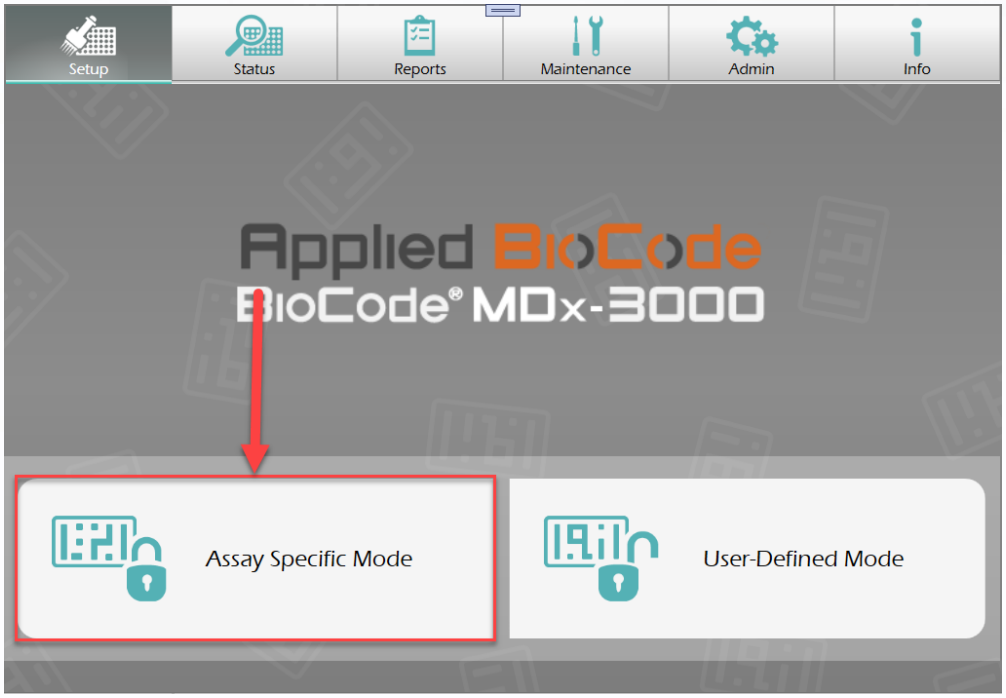
1. Follow universal safety procedures.
2. Dispose of unused kit reagents according to local, state, and federal regulations.
3. Wear appropriate personal protective equipment including, but not limited to, lab coats, gloves, and protective eyewear. Change gloves often.
4. Safety Data Sheets for all reagents provided in the STI+ Panel can be accessed at https://www.apbiocode.com/resources.
5. Do not pipette by mouth.

REAGENT STORAGE, HANDLING, AND STABILITY

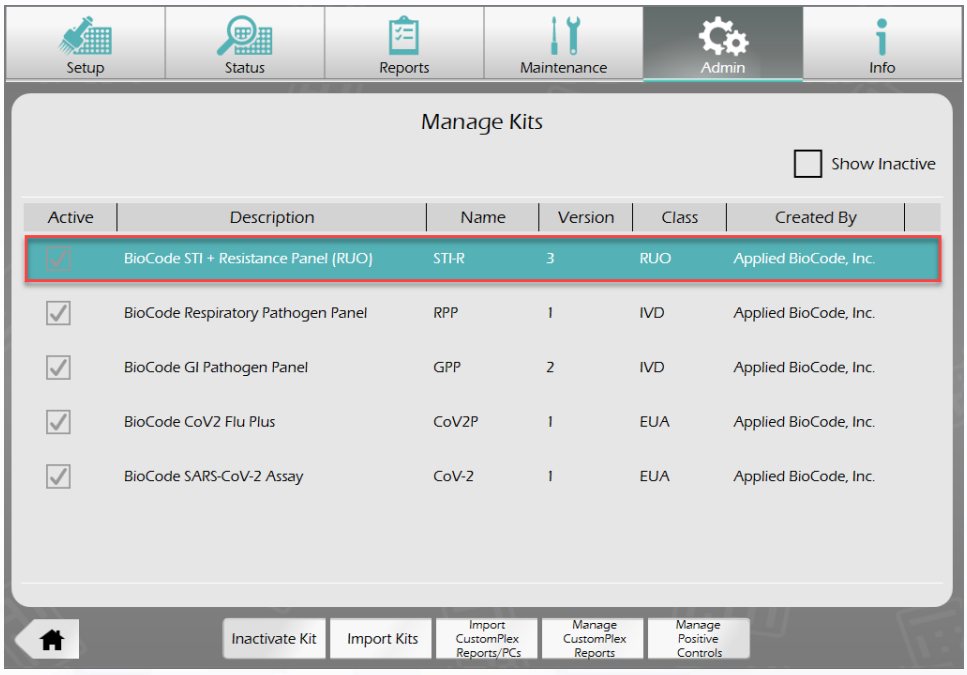
1. Store the kit components frozen (-30°C to -10°C) prior to use.
2. Once thawed, store Master Mix, Primer Mix, and DNA-IC refrigerated (2-8°C) for up to 30 days.
3. Once thawed, store BMB-Probe Mix refrigerated (2-8°C) for up to 90 days. Do not mix BMB-Probe mix between kits or lots.
4. SA-PE mix is for single use only. Store refrigerated (2-8°C). Protect from light. **DO NOT FREEZE.**
5. Store Buffer A at room temperature (15-25°C).
6. Avoid storage of any materials near heating or cooling vents or in direct sunlight.
7. Always check the expiration date and do not use reagents beyond the expiration date printed.
8. Remove BMB-Probe Mix from MDx-3000 once the run is complete and store refrigerated (2-8°C).

MDx-3000 ASSAY SPECIFIC MODE RUO STI-R PROTOCOL

1. The STI+ Panel is designed to run with the Assay Specific Mode of the MDx-3000 software. The Assay Specific Mode supports running RUO protocols.



2. Load reagents and consumables as prompted by graphic user interface and run "BioCode® STI + Resistance Panel (RUO)" protocol. The RUO STI-R protocol for use with the STI+ Panel is created and provided by Applied Biocode, Inc.



ASSAY PROCEDURE

The starting material for the STI+ Panel assay is purified nucleic acid. The user should determine the method of nucleic acid purification to be used and should ensure that method is compatible with PCR. The BioCode® DNA-IC provided in the kit should be added to each sample prior to extraction and is used as an extraction, amplification, and detection control for the STI+ Panel.

For every run, it is required to include a negative control. When assessing multiple STI+ Panel kit lots simultaneously, a negative control is necessary for each individual kit lot. This control can be comprised of either 1X PBS or RNase-free water as negative matrix, spiked with the BioCode® DNA-IC.

Gloves and other Personal Protective Equipment should be used when handling reagents. Once the PCR reagents are prepared and the sample is added into the PCR plate, promptly transfer the plate to the instrument to initiate the run. Upon the run's completion, seal and discard the PCR and capture plates.

Refer to the most recent version of the BioCode® MDx-3000 User Manual for more detail and pictorial representations of the BioCode® MDx-3000 Assay Specific Mode run set up instructions, as well as instructions for viewing the Assay Specific Reports.

Nucleic Acid Purification (for Example Purposes Only)

Note: The method used for nucleic acid purification is determined by the user. This section is provided only as an example.

1. Extract nucleic acids with a method selected by the user.

STI+ Panel Assay Setup

Note: Prepare the PCR Plate in a dedicated reaction mix preparation area.

1. Thaw Primer Mix, Master Mix A, and BMB-Probe Mix at room temperature. For the Primer Mix and Master Mix A, perform a quick vortex (2-3 seconds) and centrifuge to collect reagents at the bottom of the tubes.
2. Prepare the reaction mix in a polypropylene microcentrifuge tube as described below:

Table 6. Reaction Mix Formulation

Component	Reaction Mix Volume (µL) per reaction	Reaction Mix Volume (µL) per 10 reactions
BioCode® Master Mix A	10.0 µL	100.0 µL
BioCode® STI + Res. Panel (RUO) Primer Mix	10.0 µL	100.0 µL
Reaction Mix Volume (µL)	**20.0 µL**	**200.0 µL**

3. Mix reaction mix by briefly pulse vortexing or pipetting up and down 8 to 10 times. Centrifuge to collect contents at the bottom of the tube. If proceeding immediately to PCR plate setup, reaction mix may be kept at room temperature. If not proceeding immediately to PCR plate setup, store the reaction mix at 2-8°C or in a cooling block for up to 1 hour.
4. Pipette 20 µL of reaction mix into the appropriate wells of a 96-well plate.
5. Pipette 5 µL of each extracted sample into the wells.

6. Pipette 5 µL of the negative control into the negative control well.
7. Seal plate with a pierceable foil. Store at 2-8°C or on a cooling block until ready to load onto the BioCode® MDx-3000 (not to exceed one hour from the time the reaction mix is prepared).
8. Briefly centrifuge plate to collect samples at the bottom of the plate.
9. Load plate onto the BioCode® MDx-3000.
10. Vortex BMB-Probe Mix for 30 seconds at high speed and load the vial onto the BioCode® MDx-3000. **(Note: Precipitates may appear at cold temperatures. If precipitates are present, allow the BMB-Probe Mix to warm to room temperature and vortex additional 30 seconds.)** Based on the number of wells required in the plate setup, the BioCode® MDx-3000 software calculates the bulk BMB-Probe Mix volume required and displays the volume on the screen. The BioCode® MDx-3000 automatically dispenses 50 µL of BMB-Probe Mix into each well of the optical detection plate, based on the plate setup.
11. Load reagents and consumables as prompted by graphic user interface. Refer to the BioCode® MDx-3000 User Manual for more details on RUO run setup. Start the Run.

INTERPRETATION OF RESULTS

The BioCode® MDx-3000 software will analyze data based on plate validity, sample validity, and Median Fluorescent Intensity (MFI) compared to the MFI thresholds specified in the protocol.

- The software will indicate if the positive controls (PC) are valid or invalid but will not suppress results if any of the positive controls are invalid. However, if any of the positive controls are invalid, sample results will be flagged.
- The software will indicate if the no template control (NTC) is valid or invalid; if the no template control is invalid, then the user should review results prior to release.
- The software will indicate if the negative control (NC) is valid or invalid and will suppress the results if the negative control is invalid.

Negative Control

The negative control can be RNase-free water or 1X PBS spiked with the provided DNA-IC. The negative control should go through all processing steps (extraction, amplification, and detection). At least one negative control is required for each plate/kit lot.

Table 7. Criteria for Valid Negative Control

Control	Assay Targets	DNA-IC	Recommendations
Negative Control	Not Detected	Detected	Run status: Valid. Samples can be interpreted.
	Detected	Detected	Run status: Invalid. Samples cannot be interpreted. Results suppressed by software.
	Detected or Not Detected	Not Detected	Run status: Invalid. Samples cannot be interpreted. Results suppressed by software.

Extraction (Internal) Control

It is required that the user add the DNA Internal Control (DNA-IC) supplied in the kit to each sample and negative control during extraction. The extraction control monitors the efficiency of the extraction, amplification, and detection stages of the assay. Lack of DNA-IC signal may indicate sample-associated inhibition or reagent/instrument issues. Samples suspected of being inhibitory can be repeated from extraction. If reagent or instrument issues are suspected, samples may be repeated from stored nucleic acid extracts.

Table 8. Criteria for Valid Extraction Control

Assay Targets	DNA-IC	Recommendations
Detected or Not Detected	Detected	Well status: Valid. Report all results.
Detected	Not Detected	Well status: Invalid. Sample results can be interpreted. User should review results prior to release.
Not Detected	Not Detected	Well status: Invalid. Not detected results suppressed by software. Repeat/reflex testing.

Positive Control

Every laboratory should establish its own Quality Control (QC) ranges and determine the frequency of QC testing in accordance with relevant local laws, regulations, and good laboratory practices. Positive controls (PC) can consist of well-characterized clinical samples or strains. These controls undergo amplification and detection steps at a minimum to confirm the efficacy of the kit reagents. It is recommended to include at least one PC for each plate/kit lot on a rotating basis. Well(s) labeled as PC will be monitored by the BioCode® MDx-3000 software, and the report will indicate the validity or invalidity of the result in the report header (refer to the table below). The software will not suppress results based on PC outcomes. If a PC fails to perform as expected, the user should review all samples in that batch to determine whether results should be reported.

Table 9. Criteria for Valid Positive Control

Control	Assay Targets	Recommendations
Positive Control	Expected Target Detected	Report will indicate positive control is Valid. No user intervention required.
	Expected Target Not Detected	Report will indicate positive control is Invalid. User should review results prior to release.
	Unexpected Target Detected	Report will indicate positive control is Invalid. User should review results prior to release.

No Template Control

The No Template Control (NTC) can consist of either RNase-free water or 1X PBS. Unlike the sample, the NTC does not undergo the extraction step but proceeds through amplification and detection. The NTC serves to confirm the integrity of the assay's reagents by demonstrating that no STI+ Panel target signals are detected in the absence of target sequences. Well(s) labeled as NTC will be monitored by the

BioCode® MDx-3000 software, and the report will indicate the validity or invalidity of the result in the report header (refer to the table below). The software will not suppress results based on NTC outcomes. If a NTC fails to perform as expected, the user should review all samples in that batch to determine whether results should be reported.

Table 10. Criteria for Valid No Template Control

Control	Targets	DNA IC	Recommendations
No Template Control	Not Detected	Not Detected	Report will indicate NTC is Valid. No user intervention required.
	Not Detected	Detected	Report will indicate NTC is Invalid. User should review results prior to release.
	Detected	Not Detected	Report will indicate NTC is Invalid. User should review results prior to release.

Target Pathogen Interpretation

Fluorescent signals from BMBs with the same barcode are sorted and the median fluorescence intensity (MFI) is calculated for each analyte. The BioCode® MDx software interprets the results based on the MFI threshold values set by the assay specific mode RUO STI-R protocol. If the user decides to include controls in a run, such as one or more external controls, it is recommended that the user examine the results of the control(s) prior to assessing the results for all other samples.

SNP mutations associated with macrolide resistance will be reported for MG (ID) positive specimens and SNP mutations associated with fluoroquinolone resistance will be reported for NG (ID) and MG (ID) positive specimens. Any SNP positive result will be suppressed if the corresponding ID assay(s) are not detected.

Table 11. Single target Assay names with corresponding results

Assay Name	Assay Result	Report Result	Interpretation of Results
ID: *Chlamydia trachomatis*	Detected	CT	*Chlamydia trachomatis* DNA detected.
ID: *Trichomonas vaginalis*	Detected	TV	*Trichomonas vaginalis* DNA detected.
ID: *Neisseria gonorrhoeae*	Detected	NG	*Neisseria gonorrhoeae* DNA detected.
SNP: *Neisseria gonorrhoeae* S91 WT	Detected	NG WT	*Neisseria gonorrhoeae* wildtype DNA detected.
SNP: *Neisseria gonorrhoeae* S91F MUT	Detected	NG MUT	*Neisseria gonorrhoeae* DNA is detected. S91F mutation detected.
SNP: *Neisseria gonorrhoeae* S91 WT + S91F MUT	Detected	NG WT/MUT	Mix population of *N. gonorrhoeae* WT/MUT DNA is detected. Both S91 wildtype and S91F mutation detected.

Assay Name	Assay Result	Report Result	Interpretation of Results
SNP: *Neisseria gonorrhoeae* S91 WT + S91F MUT	Not Detected	Indeterminate	*Neisseria gonorrhoeae* DNA detected. Indeterminate for both S91 wildtype and S91F mutation.
ID: *Mycoplasma genitalium*	Detected	MG	*Mycoplasma genitalium* DNA detected.
SNP: *Mycoplasma genitalium* S83I	Detected	MG S83I	*Mycoplasma genitalium* DNA is detected. S83I mutation detected.
SNP: *Mycoplasma genitalium* A2058C	Detected	MG A2058C	*Mycoplasma genitalium* DNA is detected. A2058C mutation detected.
SNP: *Mycoplasma genitalium* A2058G	Detected	MG A2058G	*Mycoplasma genitalium* DNA is detected. A2058G mutation detected.
SNP: *Mycoplasma genitalium* A2058T	Detected	MG A2058T	*Mycoplasma genitalium* DNA is detected. A2058T mutation detected.
SNP: *Mycoplasma genitalium* A2059C	Detected	MG A2059C	*Mycoplasma genitalium* DNA is detected. A2059C mutation detected.
SNP: *Mycoplasma genitalium* A2059G	Detected	MG A2059G	*Mycoplasma genitalium* DNA is detected. A2059G mutation detected.
SNP: *Mycoplasma genitalium* A2059T	Detected	MG A2059T	*Mycoplasma genitalium* DNA is detected. A2059T mutation detected.
DNA Internal Control	Detected	DNA IC	Valid Result.

BioCode® STI + Resistance Panel Reports

The analyzed BioCode® MDx-3000 results are displayed in three report formats: RUO MFI Report, RUO Run Report, and RUO Sample Report. All reports can be reviewed electronically and exported as a PDF or CSV file. The RUO MFI Report displays raw results for specimens and controls, while the RUO Run Report and Sample Reports contain interpreted results. Refer to the most recent version of the BioCode® MDx-3000 User Manual for more details and example screenshots of BioCode® MDx-3000 reports.

The RUO MFI Report displays the MFI values calculated for each well.

The RUO Run Report displays interpreted results in a tabular format for each well. Possible results by target are Detected, Not detected, Invalid, or N/A (if not ordered).

The RUO Sample Report displays results for a single well. In addition to results for each target, the Sample Report includes a result summary section which allows positive results to be reviewed at a glance. The Sample Report result summary indicates well validity based on BMB counts, background MFI, and external and internal controls. The Sample Report also includes any sample-specific comments entered during run setup.

All report headers provide traceability information for the unique Run Name, RUO Protocol used, Run Start and Run Complete times, User, Run Status, SA-PE Mix lot, Wash buffer lot, Software Version/Mode, Instrument, and External Controls. The Run Status section will specify if the run is Valid, or Invalid based

on the negative and no template (NTC) control results for the specific run/kit lot. The External Control section indicates the results for the external control (Valid, Invalid, or N/A). It is recommended to review the Run Status and Externals Controls sections prior to reviewing target results.

Example of RUO run report:

Applied BioCode
12130 Mora Dr., Unit 2, Santa Fe Springs, California 90670, USA www.ApBioCode.com

Run Report - For Research Use Only. Not for use in diagnostic procedures.

Run Name	TestPlate1	**Kit Lot**	AJ1400014 2024/10/17
Kit	STI-R.3	**SA-PE Mix**	PF1400021 2024/08/28
Run Start	2024/05/20 05:05 PM	**Wash Buffer**	PF1400011 2024/09/07
Run Complete	2024/05/20 05:06 PM	**Software Version/Mode**	1.7.8823 / RUO
User	Administrator	**Instrument**	9876543210
Run Status	Valid	**External Controls**	NC = Valid, PC = N/A, NTC = Valid

Location	A1	B1	C1	D1	E1	F1	G1	H1
Sample Type	STI-R.3-NC	Urine	Urine	Urine	Urine	Urine	Urine	Urine
Sample ID	NC	Sample-1	Sample-2	Sample-3	Sample-4	Sample-5	Sample-6	Sample-7
ID: *Chlamydia trachomatis*	--	--	--	--	--	--	⊕	--
ID: *Trichomonas vaginalis*	--	⊕	--	--	--	--	--	--
ID: *Neisseria gonorrhoeae*	--	⊕	⊕	--	--	⊕	--	⊕
SNP: *Neisseria gonorrhoeae* S91 WT	--	⊕	--	--	--	⊕	--	--
SNP: *Neisseria gonorrhoeae* S91F MUT	--	⊕	--	--	--	--	--	⊕
SNP: *Neisseria gonorrhoeae* S91 WT + S91F MUT	--	⊕	I	--	--	--	--	--
ID: *Mycoplasma genitalium*	--	⊕	⊕	⊕	⊕	⊕	⊕	⊕
SNP: *Mycoplasma genitalium* S83I	--	--	--	⊕	--	--	--	--
SNP: *Mycoplasma genitalium* A2058C	--	--	--	--	--	--	⊕	--
SNP: *Mycoplasma genitalium* A2059C	--	⊕	--	--	--	--	--	--
SNP: *Mycoplasma genitalium* A2058G	--	--	--	--	--	⊕	--	--
SNP: *Mycoplasma genitalium* A2059G	--	--	--	--	⊕	--	--	--
SNP: *Mycoplasma genitalium* A2058T	--	--	--	⊕	--	--	--	--
SNP: *Mycoplasma genitalium* A2059T	--	--	--	--	--	--	--	⊕
Specimen Quality (Swab Only)	--	--	--	--	--	--	--	--
DNA Internal Control	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕

⊕ = Detected, I = Indeterminate, -- = Not Detected,
N/A = Results Masked, ↓C = Low BMB Count, ↓BKC = Low Background BMB Count, ↑BK = High Background MFI,
‡ IC = Invalid Internal Control, ‡ NC = Invalid Negative Control, No Data = No BMBs Detected.

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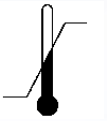
TABLE OF SYMBOLS

The following symbols are used on the STI+ Panel components and/or in this package insert.

	Batch code		Contains 96 tests		Temperature limitations
	Part Number		Warning		Consult instructions for use
	Use by YYYY-MM-DD		Registered trademark		Manufacturer