

INFINIPLEX FOR MILK —evidence— MULTISTAT

INTENDED USE

The Evidence MultiSTAT InfiniPlex for Milk (IPM) is a test array for the qualitative determination of Quinolones, Penicillins, Cephalosporins, Macrolides, Lincosamides, Aminoglycosides, Amphenicols, Diaminopyrimidines, Naphthalene ringed ansamycins, Tetracyclines, Polypeptides, Polymixins, Anti-inflammatories, Corticosteroids, Growth Promoters, Sulphonamides, Anti-parasitic drugs, Mycotoxins, Streptogramins, Novobiocin and Melamine (in parallel) in raw commingled bovine milk. They are competitive enzyme immunoassays run on the automated biochip array analyser, Evidence MultiSTAT.

FOR VETERINARY USE AND/OR THE ANALYSIS OF FOOD. Not for use in diagnostic procedures. Positive results should be confirmed by another method.

Cat. No. EV4278

Containing the following components:

1. InfiniPlex Test Cartridge	12 x 1 Cartridge
2. InfiniPlex Positive Control	3 x 1 ml
3. Sample Droppers	12 x dropper
4. InfiniPlex Reconstitution Buffer	3 x 1 ml
5. Barcode sheet	1 x Barcode Sheet

Cat. No. EV4452

Containing the following components:

1. MultiSTAT Tip Cartridge	12 x 1 Tip Cartridge
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PRINCIPLE

The Evidence MultiSTAT analyser is a fully automated Biochip Array System. It performs simultaneous detection of multiple analytes from a single sample. The core technology is the Randox Biochip, a solid-state device containing an array of discrete test regions containing immobilized antibodies specific to different food contaminants. A competitive chemiluminescent immunoassay is employed for the food contaminant assays with the drug in the sample and drug labelled with horseradish peroxidase (HRP) being in direct competition for the antibody binding sites. Increased levels of drug in a sample will lead to reduced binding of drug labelled with HRP and thus a reduction in chemiluminescence being emitted.

The light signal generated from each of the test regions on the biochip is detected using digital imaging technology and compared to that of the Reference Standard. The classification of the test analyte present in the sample is determined from the Reference Standard.

IMPORTANT REMARKS BEFORE USING INFINIPLEX

- The Evidence MultiSTAT InfiniPlex for Milk Array is designed for use only with raw bovine milk samples.
- Components are batch specific and must not be mixed with another batch of EV4278.
- NOTE: Please store MultiSTAT cartridges upright. If this is not adhered to the integrity of the cartridge may be compromised and could impact on test results. Visually check the cartridge foil for evidence of moisture or damage to foil seal. If there is any concern that the integrity of the cartridge has been compromised, do not use and contact Randox Food Diagnostics Support.
- There is a possibility that other substances and/or factors may interfere with the assays and cause erroneous results (e.g. technical or procedural errors).
- This test is qualitative. All samples that read positive in duplicate should be confirmed by another method. This confirmation method must have comparable or better sensitivity than EV4278.
- Samples can be borderline and therefore read n.d. (not detected) or positive between separate testing.
- Confirm any initial positive result (please refer to RETEST OF INITIAL PRESUMPTIVE POSITIVE section).
- Positive Control supplied in this kit must be handled carefully to avoid contamination (see PREPARATION OF POSITIVE CONTROL section).

SAMPLE COLLECTION AND PREPARATION

- Raw, commingled milk must be cooled and refrigerated. Refrigerated samples should be well mixed prior to analysis. It is recommended that milk should not be frozen at any time during the testing process. Analysis should be carried out at ambient temperatures of +15°C to +25°C.
- Frozen milk samples should be thawed well before use and show no protein precipitation. Samples that show protein precipitation, clots or sedimentation phases cannot be tested.
- Milk Samples with an abnormal pH cannot be tested (i.e. ≤ 6.5 or ≥ 7.1).
- Milk samples should be analysed prior to the addition of preservatives.
- Suitable milk samples do not require centrifugation and can be used directly.

SAFETY PRECAUTIONS AND WARNINGS

Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Reconstitution buffer contains preservative. Avoid ingestion or contact with skin or mucous membranes.

Please dispose of all biological and chemical materials according to local guidelines.

Health and Safety data sheets are available on request.

On opening the cartridge foil bag, visually check the cartridge for evidence of moisture and the cartridge foil for signs of tearing. If there is any concern that the integrity of the cartridge has been affected, do not use and contact Randox Food Diagnostics Support at support@randoxfooddiagnostics.com.

REAGENT COMPOSITION

Contents

1. **MULTISTAT INFINIPLEX ASSAY DILUENT**
20 mM phosphate buffer, pH 7.2 containing protein, detergents and preservatives. This is contained within the cartridge.
2. **MULTISTAT INFINIPLEX CONJUGATE**
Mes based buffer, pH 5.5 containing protein, preservatives and horseradish peroxidase - labelled drug derivatives. This is contained within the cartridge.
3. **MULTISTAT INFINIPLEX BIOCHIP**
Solid substrate containing immobilized antibody discrete test regions. This is contained within the cartridge.
4. **MULTISTAT INFINIPLEX WASH BUFFER**
20 mM Tris buffered saline, pH 7.4, containing surfactant and preservatives. This is contained within the cartridge.
5. **LUM-EV934/PX**
Luminol-EV934 and Peroxide are contained within the cartridge and are mixed in a ratio of 1:1 by the analyser to give the working signal reagent.
6. **MULTISTAT INFINIPLEX REFERENCE STANDARD**
Liquid buffer contained within the cartridge.
7. **MULTISTAT INFINIPLEX POSITIVE CONTROL**
Lyophilised, 20 mM phosphate buffer, pH 7.2 containing stabilizers, preservatives and drug concentrations as outlined below.
8. **MULTISTAT RECONSTITUTION BUFFER**
A solution at a neutral pH containing preservatives.

STABILITY AND PREPARATION OF REAGENTS

1. **MULTISTAT INFINIPLEX TEST CARTRIDGE**
The test cartridge is ready for use and is stable up to the expiry date when stored in the foil bag at +2°C to +8°C, protected from light. Test cartridges must be brought to room temperature for at least 30 minutes before opening. Once removed from the foil bag the cartridge must be used immediately.
2. **MULTISTAT INFINIPLEX POSITIVE CONTROL**
Lyophilised positive controls are stable until the expiry date when stored unopened, at +2 to +8°C. The reconstituted Positive control is stable for 8 hours when stored at +15 to +25°C. For long term storage, the reconstituted positive control can be stored at ≤ -20°C or below for up to 31 days. However, after reconstitution it must be aliquoted and frozen within 30 mins. Thaw slowly and mix well before use. Once thawed it is stable for 8 hours when stored at +2 to +8°C. Discard after use, **Do not refreeze**.
3. **MULTISTAT RECONSTITUTION BUFFER**
Reconstitution Buffer is ready for use and is stable up to the expiry date when stored at +2 to +8°C protected from light.

PROCEDURE

BATCH UPDATE FROM USB

Upon receipt of a new batch of EV4278 a batch specific update will have to be completed from the USB provided:

- Scan the cartridge barcode – when scanned for the first time this will prompt the user to import the batch details from the provided USB.
- Insert the USB into the USB port located on the bottom right hand side or on the back of the analyser below the power button.
- Once the USB has been connected select the import data button on screen.
- Select the batch update and select OK.
- A loading screen will appear briefly and the batch update will now be complete.
- For each batch, an initial 'Batch QC' must be run on the analyser, this will consist of running the provided positive control material as indicated in the assay protocol section.

For further information please refer to the Evidence MultiSTAT Operators Manual.

PREPARATION OF POSITIVE CONTROL

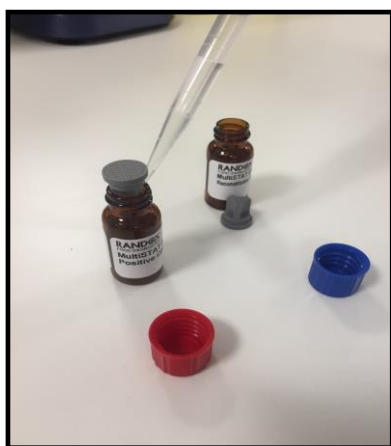
The Positive Control material is presented as an amber glass vial containing a cocktail of different freeze-dried analytes specific to each of the 43 tests.

NOTE: Positive Control supplied in this kit must be handled carefully to avoid contamination

To prepare the positive control follow one of the options and associated steps outlined below:

Option 1 – With a calibrated Pipette

Carefully open bung (do not remove bung completely) and reconstitute one vial with 1 ml of reconstitution buffer and invert several times. Leave to stand for 20mins. Avoid the formation of foam until completely dissolved before use.



Option 2 – With reconstitution buffer provided

Take a glass vial of reconstitution buffer (blue cap)



Remove the cap and bung carefully avoiding the loss of any material. Ensure the bung is kept upright until replaced back into vial.

Repeat steps for the Positive Control (red cap).



Pour the reconstitution buffer into the positive control vial.



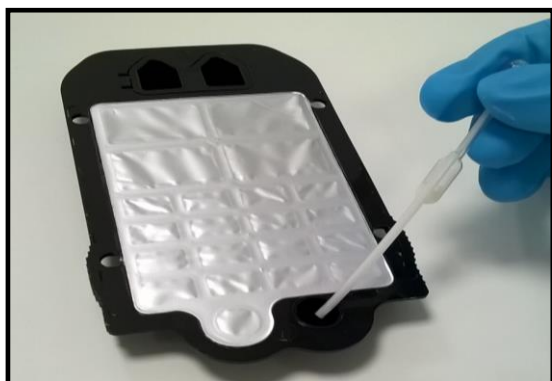
Replace the same bung and cap onto the vial and leave to stand for 20mins. Invert several times to help mixing.



Ensure the area is cleaned down after preparation to avoid contamination.

HOW TO PREPARE A CARTRIDGE AND SAMPLE

1. Choose a clean and dry place to perform the test. Wash and dry your hands before starting. Leave cartridge sealed in foil bag and sample for 30 minutes at +15 to +25°C.
2. Open foil bag and remove cartridge carefully (avoid damaging foil on the cartridge). Inspect the cartridge to ensure there are no tears or leaks. If the cartridge has been stored incorrectly, please refer to 'Important remarks before using InfiniPlex' section.
3. Use the sample pipette (provided in the kit) and pipette a minimum of 500 µl of sample or positive control into the open sample well on the right as indicated below. Squeeze the bulb of the pipette, place the pipette into the sample and release pressure on bulb. Squeeze bulb again to release sample onto cartridge. Do not aspirate the reagent back into pipette.



4. The cartridge is now ready to be inserted carefully into the Evidence MultiSTAT analyser along with a new tip cartridge (Catalogue Number EV4452) ready for analysis.

ARRAY CONFIGURATION

The analytes to be reported can be disabled/enabled by an administrator. Please refer to the Array Configuration section in the Operators Manual for further details.

CARTRIDGE ANALYSIS

Please refer to the Operators Manual for general operating procedure.

RESULTS PROCESSING

Results are processed automatically using the dedicated software.

Different reporting options are available to select one of these reporting options contact Randox Food Diagnostics Support at support@randoxfooddiagnostics.com.

QUALITATIVE ANALYSIS

Each test sample is assayed against the provided reference standard material which is used to determine the classification of the samples. (Refer to Evidence MultiSTAT Operators Manual for additional information.)

QUALITY CONTROL

Evidence MultiSTAT® IPM Positive Control Material is provided with the kit and is required to run the initial batch QC upon receipt of the kit. Following this the Batch QC must be repeated at 30-day intervals. The positive control material can be assayed more frequently at the discretion of the user. Control results should be acceptable, otherwise corrective action should be taken as established by laboratory guidelines.

INSTRUMENT SETTINGS

Instrument settings are included in the batch update.

How to Test on Infiniplex for Milk MultiSTAT (IPM)



Screen Sample on IPM

**POSITIVE, POSITIVE (+),
POSITIVE (++), POSITIVE (+++)**



Sample reported as **POSITIVE** for the presumptive positive analyte(s) only.
(Refer to results interpretation section)

n.d



Sample is negative
and therefore
reported as n.d.



Retest of initial presumptive positive (Refer to
Retest of initial presumptive positive section)

**POSITIVE, POSITIVE (+),
POSITIVE (++), POSITIVE (+++)**



Retest of sample is positive and
therefore reported as **POSITIVE**.
This sample should be confirmed
by **another method**.

n.d.



Retest of Sample is
negative and therefore
reported as n.d.

RESULT INTERPRETATION

This test is qualitative. All samples that read positive in duplicate should be confirmed by another method. This confirmation method must have comparable or better sensitivity than EV4278.

Samples can read negative or positive between separate testing when close to the decision level.

All results are stored on the MultiSTAT. Please refer to the Operators Manual for further details.

The device will only calculate and report results for the analytes selected by the user. It is the responsibility of the user to ensure they have selected the correct analytes at the time of testing.

In all access levels ("User Access" or "Administrator Access") the final results of the test will be displayed on the screen in one of the following 'Classification Options' depending on the reporting option requested by the user:

Classification Option: Report n.d. / POSITIVE (i.e. results are displayed as either n.d. / POSITIVE)

Classification Option: Report Positivity Classification (i.e. results are displayed as either n.d. / POSITIVE (+) / POSITIVE (++) / POSITIVE (+++))
(Please see below)

Example screen results with Classification Option - Report n.d. / POSITIVE

n.d. RESULT

Result:	Completed	User Name:	rdx.manufacture	Batch QC Date:	28/03/2018 13:31
Analytes Detected:	0	Array Name:	InfiniPlex for Milk	Batch QC ID:	85213
Cartridge ID:	85215	Sample ID:	370342		
Date Run:	28/03/2018 14:17	Barcode:	MIM01050045118101234567		

Analyte	Result	Decision Level	Analyte	Result	Decision Level	Analyte	Result	Decision Level
RIFAXIMIN	n.d.	1 ppb	AFLATOXINM1	n.d.	0.038 ppb	METHYLPREDNISOLONE	n.d.	<=>
VIRGINIAMYCIN	n.d.	0.75 ppb	NITROXYNIL	n.d.	1.5 ppb	BETA-LACTAM	n.d.	<=>
HYDROXYLINDIN	n.d.	<=>	KANAMYCIN	n.d.	4 ppb	RACLOPAMINE	n.d.	0.32 ppb
BAQUILOPRIM	n.d.	3 ppb	POLYMDINS	n.d.	<=>	MELAMINE	n.d.	24 ppb
TELPIROSIN	n.d.	<=>	AMPHENICOLS	n.d.	<=>	SULPHONAMIDES	n.d.	<=>
PHENYLBUTAZONE	n.d.	<=>	SULPHAMETHAZINE	n.d.	<=>	STREPTOMYCIN	n.d.	<=>
TRIMETHOPRIM	n.d.	13 ppb	MELOXICAM	n.d.	6 ppb	SULPHAGUANIDINE	n.d.	50 ppb
MELAMINE	n.d.	625 ppb	TOLFENAMIC ACID	n.d.	1.6 ppb	ERYTHROMYCIN	n.d.	<=>
CEPHALEXIN	n.d.	23 ppb	TRIPLENNAMINE	n.d.	4 ppb	SULPHAPYRIDINE	n.d.	<=>
DAPSONE	n.d.	<=>	TETRACYCLINES	n.d.	<=>	PRIMUMYCIN	n.d.	11 ppb
CHLORAMPHENICOL	n.d.	2 ppb	LINCOMYCIN	n.d.	6.5 ppb	CHLORMANIDONE	n.d.	1.2 ppb
CEFUROXIME	n.d.	8.5 ppb	TYLOSIN	n.d.	7.5 ppb	SPECTINOMYCIN	n.d.	3 ppb
NOVOBIOCCIN	n.d.	12.5 ppb	CORTICOSTEROIDS	n.d.	<=>	QUINOLONES	n.d.	<=>
SPRIMYCIN	n.d.	<=>	NEOMYCIN	n.d.	<=>	APRAMYCIN	n.d.	6 ppb
GENTAMICIN	n.d.	22 ppb						

<=> Analyte concentration equivalence; This is a broad spectrum assay; refer to IFU for full decision levels

* n.d. = Not Detected

IFU RLU Values Reprocess Results List Export

Power ? Logout Lock Home Basic Search Advanced Search Results

A n.d. (not detected) result indicates the absence of an analyte in the sample, or a presence at a concentration lower than its decision level.

A sample that is n.d. for all reporting tests is negative and requires no further testing.

POSITIVE RESULT

Result:	Completed	User Name:	rdx.manufacture	Batch QC Date:	05/04/2018 17:15
Analytes Detected:	3	Array Name:	InfiniPlex for Milk	Batch QC ID:	85157
Cartridge ID:	85175	Sample ID:	052-16-0020 1234567		
Date Run:	08/05/2018 10:49	Barcode:	MIM01050045118101234567		

Analyte	Result	Decision Level	Analyte	Result	Decision Level	Analyte	Result	Decision Level
RIFAXIMIN	n.d.	1 ppb	SULPHONAMIDES	n.d.	<=>	AMPHENICOLS	n.d.	<=>
VIRGINIAMYCIN	n.d.	0.75 ppb	MELAMINE	n.d.	24 ppb	TRIMETHOPRIM	n.d.	13 ppb
HYDROXYLINDIN	n.d.	<=>	RACLOPAMINE	n.d.	0.32 ppb	MELAMINE	n.d.	625 ppb
BAQUILOPRIM	n.d.	3 ppb	BETA-LACTAM	Positive	<=>	CEPHALEXIN	n.d.	23 ppb
TELPIROSIN	n.d.	<=>	METHYLPREDNISOLONE	n.d.	<=>	DAPSONE	n.d.	<=>
PHENYLBUTAZONE	n.d.	<=>	NEOMYCIN	n.d.	<=>	CHLORAMPHENICOL	n.d.	2 ppb
APRAMYCIN	n.d.	6 ppb	CORTICOSTEROIDS	n.d.	<=>	CEFUROXIME	n.d.	8.5 ppb
QUINOLONES	n.d.	<=>	TYLOSIN	n.d.	7.5 ppb	NOVOBIOCCIN	n.d.	12.5 ppb
SPECTINOMYCIN	n.d.	3 ppb	LINCOMYCIN	n.d.	6.5 ppb	SPRIMYCIN	n.d.	<=>
CHLORMANIDONE	n.d.	1.2 ppb	TETRACYCLINES	n.d.	<=>	GENTAMICIN	n.d.	22 ppb
PRIMUMYCIN	n.d.	11 ppb	TRIPLENNAMINE	n.d.	4 ppb	AFLATOXINM1	Positive	0.038 ppb
SULPHAPYRIDINE	n.d.	<=>	TOLFENAMIC ACID	n.d.	1.6 ppb	NITROXYNIL	Positive	1.5 ppb
ERYTHROMYCIN	n.d.	<=>	MELOXICAM	n.d.	6 ppb	KANAMYCIN	n.d.	4 ppb
SULPHAGUANIDINE	n.d.	50 ppb	SULPHAMETHAZINE	n.d.	<=>	POLYMDINS	n.d.	<=>
STREPTOMYCIN	n.d.	<=>						

<=> Analyte concentration equivalence; This is a broad spectrum assay; refer to IFU for full decision levels

* n.d. = Not Detected

IFU RLU Values Reprocess Results List Export

Power ? Logout Lock Home Basic Search Advanced Search Results

An initial POSITIVE result may indicate the presence of at least one analyte in the sample at a concentration equal or higher than its decision level. This is a presumptive positive sample. This sample needs to be confirmed by another IPM Cartridge.

If a result is POSITIVE and displays a unique value for the decision level (e.g. 1ppb) then this indicates that the positive is caused by the analyte indicated.

If a result is POSITIVE and displays the symbol <=> under the decision level, then this indicates that the sample has detected positive on a broad-spectrum assay. The user must refer to this IFU for a full list of decision levels. The user can display the IFU for InfiniPlex by selecting IFU button on screen.

Refer to RETEST OF INITIAL PRESUMPTIVE POSITIVE section.

Example screen results with Classification Option - 'Report Positivity Classification' (i.e. n.d. / POSITIVE (+) / POSITIVE (++) / POSITIVE (+++))

n.d. RESULT

Result:	Completed	User Name:	rdx.manufacture	Batch QC Date:	28/03/2018 13:31
Analytes Detected:	0	Array Name:	InfiniPlex for Milk	Batch QC ID:	85213
Cartridge ID:	85215	Sample ID:	370342		
Date Run:	28/03/2018 14:17	Barcode:	MIMO1050045118101234567		

Analyte	Result	Decision Level	Analyte	Result	Decision Level	Analyte	Result	Decision Level
RIFAXIMIN	n.d.	1 ppb	AFATOXINM1	n.d.	0.038 ppb	METHYLPREDNISOLONE	n.d.	<=>
VIRGINIAMYCIN	n.d.	0.75 ppb	NITROXYNIL	n.d.	1.5 ppb	BETA-LACTAM	n.d.	<=>
HYDROXYFLUNDON	n.d.	<=>	KANAMYCIN	n.d.	4 ppb	RACOPAMINE	n.d.	0.32 ppb
BAQUILOPRIM	n.d.	3 ppb	POLYMXINS	n.d.	<=>	METAMIZOLE	n.d.	24 ppb
TILDIPROSIN	n.d.	<=>	AMPHENICOLS	n.d.	<=>	SULPHONAMIDES	n.d.	<=>
PHENYLETHAZONE	n.d.	<=>	SULPHAMETHAZINE	n.d.	<=>	STREPTOMYCIN	n.d.	<=>
TRIMETHOPRIM	n.d.	13 ppb	MELOXICAM	n.d.	5 ppb	SULPHAGUANIDINE	n.d.	50 ppb
MELAMINE	n.d.	625 ppb	TOUFENAMIC ACID	n.d.	1.6 ppb	ERYTHROMYCIN	n.d.	<=>
CEPHALEXIN	n.d.	23 ppb	TRIPLENNAMINE	n.d.	4 ppb	SULPHAPYRIDINE	n.d.	<=>
DAPSONE	n.d.	<=>	TETRACYCLINES	n.d.	<=>	PRILIMYCIN	n.d.	11 ppb
BACTRACIN	n.d.	2 ppb	LINCOMYCIN	n.d.	6.5 ppb	CHLORMADINONE	n.d.	1.2 ppb
CEFUROXIME	n.d.	8.5 ppb	TYLOSIN	n.d.	7.5 ppb	SPECTINOMYCIN	n.d.	3 ppb
NOVOBIOICIN	n.d.	12.5 ppb	CORTICOSTEROIDS	n.d.	<=>	QUINOLONES	n.d.	<=>
SPRAMYCIN	n.d.	<=>	NEOMYCIN	n.d.	<=>	APRAMYCIN	n.d.	6 ppb
GENTAMICIN	n.d.	22 ppb						

<=> Analyte concentration equivalence: This is a broad spectrum assay; refer to IFU for full decision levels

* n.d. = Not Detected

IFU RUI Values Reprocess Results List Export

Power ? Logout Lock Home Basic Search Advanced Search Results

A n.d. (not detected) result indicates the absence of an analyte in the sample, or a presence at a concentration lower than its decision level.

A sample that is n.d. for all reporting tests is negative and requires no further testing.

POSITIVE RESULT

Result:	Valid	User Name:	rdx.manufacture	Batch QC Date:	04/07/2019 17:27
Analytes Detected:	4	Array Name:	InfiniPlex for Milk (Test)	Batch QC ID:	85082
Cartridge ID:	85086	Sample ID:	RDX15123456_0000034		
Date Run:	04/07/2019 17:37	Barcode:	FOD01050083130111234567		

Analyte	Result	Decision Level	Analyte	Result	Decision Level	Analyte	Result	Decision Level
RIFAXIMIN	n.d.	1 ppb	SULPHONAMIDES	n.d.	<=>	AMPHENICOLS	n.d.	<=>
VIRGINIAMYCIN	n.d.	0.75 ppb	METAMIZOLE	n.d.	<=>	TRIMETHOPRIM	n.d.	4 ppb
HYDROXYFLUNDON	n.d.	<=>	RACOPAMINE	n.d.	0.6 ppb	MELAMINE	n.d.	<=>
BAQUILOPRIM	n.d.	6 ppb	BETA-LACTAM	POSITIVE (++)	<=>	CEPHALEXIN	n.d.	7.5 ppb
TILDIPROSIN	n.d.	<=>	METHYLPREDNISOLONE	n.d.	<=>	DAPSONE	n.d.	<=>
PHENYLETHAZONE	n.d.	<=>	NEOMYCIN	POSITIVE (+)	<=>	BACTRACIN	n.d.	1 ppb
APRAMYCIN	n.d.	5 ppb	CORTICOSTEROIDS	n.d.	<=>	CEFUROXIME	n.d.	9 ppb
QUINOLONES	n.d.	<=>	TYLOSIN	n.d.	<=>	NOVOBIOICIN	POSITIVE (++)	5 ppb
SPECTINOMYCIN	n.d.	4 ppb	LINCOMYCIN	n.d.	14 ppb	SPRAMYCIN	n.d.	<=>
CHLORMADINONE	n.d.	8 ppb	TETRACYCLINES	n.d.	<=>	GENTAMICIN	n.d.	60 ppb
PRILIMYCIN	n.d.	25 ppb	TRIPLENNAMINE	n.d.	5 ppb	AFATOXINM1	n.d.	0.04 ppb
SULPHAPYRIDINE	n.d.	<=>	TOUFENAMIC ACID	n.d.	2 ppb	NITROXYNIL	n.d.	15 ppb
ERYTHROMYCIN	n.d.	<=>	MELOXICAM	n.d.	4 ppb	KANAMYCIN	n.d.	30 ppb
SULPHAGUANIDINE	n.d.	22 ppb	SULPHAMETHAZINE	n.d.	<=>	POLYMXINS	n.d.	<=>
STREPTOMYCIN	POSITIVE (++)	<=>						

<=> Analyte concentration equivalence: This is a broad spectrum assay; refer to IFU for full decision levels. * n.d. = Not Detected
Positive (+), Positive (++) = Indicates the level of positivity.

IFU RUI Values Reprocess Results List Export

Power ? Logout Lock Home Basic Search Advanced Search Results

An initial POSITIVE result may indicate the presence of at least one analyte in the sample at a concentration equal or higher than its decision level. This is a presumptive positive sample. This sample needs to be confirmed by another IPM Cartridge.

With Classification Option - 'Report Positivity Classification' selected an initial POSITIVE result may be reported as POSITIVE (+), POSITIVE (++) or POSITIVE (+++). This indicates the level of positivity of a sample relative to the decision level of the test.

If a result is POSITIVE and displays a unique value for the decision level (e.g. 1 ppb) then this indicates that the positive is caused by the analyte indicated.

If a result is POSITIVE and displays the symbol <=> under the decision level then this indicates that the sample has detected positive on a broad-spectrum assay. The user must refer to this IFU for a full list of decision levels. The user can display the IFU for InfiniPlex by selecting IFU button on screen.

Refer to RETEST OF INITIAL PRESUMPTIVE POSITIVE section.

RETEST OF INITIAL PRESUMPTIVE POSITIVE (see point 2 on flow diagram - How to Test on IPM)

1. Test "Initial Presumptive Positive" sample with a further InfiniPlex Cartridge.
2. Before running the retest, only the analytes that are presumptive positive should be selected (as detailed in the array configuration section).
3. Users with 'Report Positivity Classification' Access should re run the sample as instructed on page 5 irrespective of the indicated level of positivity.

NOTE: Ensure that all analytes of interest have been re-selected (as outlined in array configuration section of the Operator manual) before screening any NEW sample. Failure to do this may result in some analytes of interest not being reported by the MultiSTAT.

PERFORMANCE INFORMATION:

The Decision Level corresponds to the concentration where $\geq 95\%$ of the samples tested are positive. The decision levels stated in this IFU are preliminary and are subject to change.

Table 1 details the decision levels for each residue from discrete test regions (DTR) arrayed on the biochip. This is not an exhaustive list; certain tests are sensitive to other drugs. Sole reliance on the use of this test kit may result in rejection of milk which the region regulatory body may consider safe for human consumption.

Table 1:

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Rifaximin	3	Rifaximin (RFX)	Naphthalene ringed ansamycins

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Virginiamycin M1	1	Virginiamycin (VIR)	Streptogramins

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
5-OH Flunixin	0.5	5-OH Flunixin (HFLU)	Anti-inflammatory
Flunixin	0.8	5-OH Flunixin (HFLU)	Anti-inflammatory

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Baquiloprim	6	Baquiloprim (BQP)	Diaminopyrimidine

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Tildipirosin	1.3	Tildipirosin (TIL)	Macrolide
Tilmicosin	5	Tildipirosin (TIL)	Macrolide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Phenylbutazone	1.1	Phenylbutazone (PBZ)	Anti-inflammatory
Oxyphenbutazone	0.75	Phenylbutazone (PBZ)	Anti-inflammatory

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Apramycin	8	Apramycin (APA)	Aminoglycoside

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Enrofloxacin	1.5	Quinolones (QNL)	Quinolone
Ciprofloxacin	2	Quinolones (QNL)	Quinolone
Flumequine	7	Quinolones (QNL)	Quinolone
Danofloxacin	3	Quinolones (QNL)	Quinolone
Difloxacin	5	Quinolones (QNL)	Quinolone
Marbofloxacin	5.75	Quinolones (QNL)	Quinolone
Oxolinic acid	5	Quinolones (QNL)	Quinolone
Perfloxacin	1	Quinolones (QNL)	Quinolone
Norfloxacin	1	Quinolones (QNL)	Quinolone
Ofloxacin	3.25	Quinolones (QNL)	Quinolone

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Spectinomycin	4	Spectinomycin (SPT)	Aminoglycoside

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Chlormadinone	8	Chlormadinone (CM)	Anti-inflammatory

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Pirlimycin	25	Pirlimycin (PIRLI)	Lincosamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Sulphapyridine	5	Sulphapyridine (SP)	Sulphonamide
Sulphaethoxypyridazine	47	Sulphapyridine (SP)	Sulphonamide
Sulphamethoxypyridazine	43	Sulphapyridine (SP)	Sulphonamide
Sulphamoxol	65	Sulphapyridine (SP)	Sulphonamide
Sulphasalazine	4.7	Sulphapyridine (SP)	Sulphonamide
Sulphanitran	150	Sulphapyridine (SP)	Sulphonamide
Sulphathiazole	150	Sulphapyridine (SP)	Sulphonamide
Sulphamonomethoxine	>400	Sulphapyridine (SP)	Sulphonamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Erythromycin	4	Erythromycin (ERY)	Macrolide
Gamithromycin	600	Erythromycin (ERY)	Macrolide
Tulathromycin	>1100	Erythromycin (ERY)	Macrolide
Oleandomycin	>1500	Erythromycin (ERY)	Macrolide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Sulphaguanidine	22	Sulphaguanidine (SFG)	Sulphonamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Streptomycin	45	Streptomycin (STR)	Aminoglycoside
Dihydrostreptomycin	35	Streptomycin (STR)	Aminoglycoside

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Sulphadiazine	7.5	Sulphonamides (SULPH)	Sulphonamide
Sulphaquinoxaline	2.3	Sulphonamides (SULPH)	Sulphonamide
Sulphadimethoxine	1.8	Sulphonamides (SULPH)	Sulphonamide
Sulphacetamide	1	Sulphonamides (SULPH)	Sulphonamide
Sulphadoxine	1.5	Sulphonamides (SULPH)	Sulphonamide
Sulphabenzamide	0.75	Sulphonamides (SULPH)	Sulphonamide
Sulphamethoxazole	2.5	Sulphonamides (SULPH)	Sulphonamide
Sulphamonomethoxine	1	Sulphonamides (SULPH)	Sulphonamide
Sulphachlorpyridazine	2.25	Sulphonamides (SULPH)	Sulphonamide
Sulphathiazole	16	Sulphonamides (SULPH)	Sulphonamide
Sulphamethoxypyridazine	43	Sulphonamides (SULPH)	Sulphonamide
Sulfisoxazole	0.7	Sulphonamides (SULPH)	Sulphonamide
Sulphamerazine	70	Sulphonamides (SULPH)	Sulphonamide
Sulphamethizole	7.5	Sulphonamides (SULPH)	Sulphonamide
Sulphameter	4.5	Sulphonamides (SULPH)	Sulphonamide
Sulphamoxol	60	Sulphonamides (SULPH)	Sulphonamide
Sulphanitran	28	Sulphonamides (SULPH)	Sulphonamide
Sulphaphenazole	2.5	Sulphonamides (SULPH)	Sulphonamide
Sulphatroxazole	0.75	Sulphonamides (SULPH)	Sulphonamide
Sulfisomidine	15	Sulphonamides (SULPH)	Sulphonamide
Sulphaethoxypyridazine	25	Sulphonamides (SULPH)	Sulphonamide
Sulphapyridine	60	Sulphonamides (SULPH)	Sulphonamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Metamizole (Dipyrone)	17	Metamizole (MTM)	Anti-inflammatory
4-Methylaminoantipyrin	20	Metamizole (MTM)	Anti-inflammatory

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Ractopamine	0.5	Ractopamine (RP)	Growth Promoter

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Penicillin G (Benzylpenicillin)	0.75	Beta-Lactams (BLACT)	Penicillin
Ampicillin	3	Beta-Lactams (BLACT)	Penicillin
Dicloxacillin	1.35	Beta-Lactams (BLACT)	Penicillin
Amoxicillin	1.9	Beta-Lactams (BLACT)	Penicillin
Cloxacillin	3	Beta-Lactams (BLACT)	Penicillin
Oxacillin	3.75	Beta-Lactams (BLACT)	Penicillin
Nafcillin	6.75	Beta-Lactams (BLACT)	Penicillin
Penicillin V (Phenoxymethylpenicillin)	1.5	Beta-Lactams (BLACT)	Penicillin
Penicillin G Procaine	1.9	Beta-Lactams (BLACT)	Penicillin
Penethamate	6.5	Beta-Lactams (BLACT)	Penicillin
Benzathine Benzylpenicillin	2	Beta-Lactams (BLACT)	Penicillin
Cefalonium	1.25	Beta-Lactams (BLACT)	Cefalosporin
Cefoperazone	1.75	Beta-Lactams (BLACT)	Cefalosporin
Cefapirin	15	Beta-Lactams (BLACT)	Cefalosporin
Desacetylcefapirin	25	Beta-Lactams (BLACT)	Cefalosporin
Cefquinome	5.5	Beta-Lactams (BLACT)	Cefalosporin
Ceftiofur	89	Beta-Lactams (BLACT)	Cefalosporin
Cefacetril	32	Beta-Lactams (BLACT)	Cefalosporin
Cefazolin	>50	Beta-Lactams (BLACT)	Cefalosporin
Cefalothin	14	Beta-Lactams (BLACT)	Cefalosporin
Desfuoyl Ceftiofur	<100	Beta-Lactams (BLACT)	Cefalosporin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Cefazolin	1.5	Cefazolin (CEFA)	Cefalosporin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Methylprednisolone	0.6	Methylprednisolone (MEP)	Corticosteroid
Prednisolone	2.5	Methylprednisolone (MEP)	Corticosteroid

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Neomycin	35	Neomycin (NEO)	Aminoglycoside
Paromomycin	30	Neomycin (NEO)	Aminoglycoside
Framycetin	45	Neomycin (NEO)	Aminoglycoside

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Dexamethasone	0.25	Dexamethasone (DEXA)	Corticosteroid
Betamethasone	1	Dexamethasone (DEXA)	Corticosteroid

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Tylosin A	6	Tylosin (TYL)	Macrolide
Tilmicosin	8	Tylosin (TYL)	Macrolide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Lincomycin	10	Lincomycin (LIN)	Lincosamide
Clindamycin	9	Lincomycin (LIN)	Lincosamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Tetracycline	3.75	Tetracycline (TCN)	Tetracycline
Chlortetracycline	4.75	Tetracycline (TCN)	Tetracycline
Oxytetracycline	3.75	Tetracycline (TCN)	Tetracycline
Doxycycline	5.5	Tetracycline (TCN)	Tetracycline
4-epimer chlorotetracycline	9.5	Tetracycline (TCN)	Tetracycline
4-Epitetracycline	6.75	Tetracycline (TCN)	Tetracycline
4-Epioxyteracycline	7.5	Tetracycline (TCN)	Tetracycline

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Tripelennamine	5	Tripelennamine (TRIP)	Antihistamine

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Tolfenamic Acid	2.5	Tolfenamic Acid (TA)	Anti-inflammatory
Flunixin	1.9	Tolfenamic Acid (TA)	Anti-inflammatory
5-hydroxy Flunixin	>55	Tolfenamic Acid (TA)	Anti-inflammatory

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Meloxicam	4.5	Meloxicam (MLX)	Anti-inflammatory

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Sulphamethazine (Sulphadimidine)	2	Sulphamethazine (SMT)	Sulphonamide
Sulphamerazine	37.5	Sulphamethazine (SMT)	Sulphonamide
Sulphamoxol	450	Sulphamethazine (SMT)	Sulphonamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Chloramphenicol	0.15	Amphenicols (AMP)	Amphenicol
Thiamphenicol	1.75	Amphenicols (AMP)	Amphenicol
Florfenicol	0.2	Amphenicols (AMP)	Amphenicol

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Trimethoprim	2	Trimethoprim (TMP)	Diaminopyrimidine

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Cefalexin	7	Cefalexin (CEX)	Cefalosporin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Dapsone	0.9	Dapsone (DAPS)	Sulphonamide
Sulphathiazole	17	Dapsone (DAPS)	Sulphonamide
Sulphadoxine	25	Dapsone (DAPS)	Sulphonamide
Sulphadimethoxine	6	Dapsone (DAPS)	Sulphonamide
Sulphanitran	70	Dapsone (DAPS)	Sulphonamide
Sulphapyridine	50	Dapsone (DAPS)	Sulphonamide
Sulphaquinoxaline	5	Dapsone (DAPS)	Sulphonamide
Sulphamerazine	15	Dapsone (DAPS)	Sulphonamide
Sulphamonomethoxine	57	Dapsone (DAPS)	Sulphonamide
Sulphadiazine	25	Dapsone (DAPS)	Sulphonamide
Sulphamethoxypyridazine	43	Dapsone (DAPS)	Sulphonamide
Sulphamethizole	27.5	Dapsone (DAPS)	Sulphonamide
Sulphameter	7.5	Dapsone (DAPS)	Sulphonamide
Sulfisomidine	15	Dapsone (DAPS)	Sulphonamide
Sulphamethazine	20	Dapsone (DAPS)	Sulphonamide
Sulphaethoxypyridazine	25	Dapsone (DAPS)	Sulphonamide
Sulphamethoxazole	95	Dapsone (DAPS)	Sulphonamide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Bacitracin	1.75	Bacitracin (BCT)	Polypeptide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Cefuroxime	7	Cefuroxime (CXM)	Cefalosporin
Ceftiofur	>100ppb	Cefuroxime (CXM)	Cefalosporin
Desfuoyl Ceftiofur	>100ppb	Cefuroxime (CXM)	Cefalosporin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Novobiocin	3	Novobiocin (NOVO)	Aminocoumarin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Spiramycin	30	Spiramycin (SPR)	Macrolide
Neospiramycin	125	Spiramycin (SPR)	Macrolide

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Gentamycin	0.875	Gentamicin (GEN)	Aminoglycoside

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Aflatoxin M1	0.045	Aflatoxin M1 (AFM1)	Mycotoxin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Nitroxylin	2	Nitroxylin (NITR)	Antiparasitic

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Kanamycin A	30	Kanamycin (KANA)	Aminoglycoside

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Colistin	2	Polymixins (PM)	Polymixin
Polymixin B	1.5	Polymixins (PM)	Polymixin

Detectable Residues	Decision Level (ppb)	Assay name (Abbreviation)	Residue Group
Melamine	150	Melamine (MLM)	Cyanamide
Cyromazine	12.5	Melamine (MLM)	Cyanamide