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Header @ 1

List View

General Information | Contact | Default Values | Discount | Document Information | Clarification Request

Procurement Folder: 1241705

Procurement Type: Central Master Agreement

Vendor ID: VC0000006995

Legal Name: BIOCHEK USA CORP

Alias/DBA:

Total Bid: \$68,040.00

Response Date: 06/26/2023

Response Time: 11:37

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SO Doc Code: CRFQ

SO Dept: 1400

SO Doc ID: AGR2300000034

Published Date: 6/9/23

Close Date: 6/27/23

Close Time: 13:30

Status: Closed

Solicitation Description: MYCOPLASMA MELEAGRIDIS ELISA TESTING KITS

Total of Header Attachments: 1

Total of All Attachments: 1



Department of Administration
 Purchasing Division
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**State of West Virginia
 Solicitation Response**

Proc Folder: 1241705
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Solicitation Closes	Solicitation Response	Version
2023-06-27 13:30	SR 1400 ESR06262300000006551	1

VENDOR
 VC0000006995
 BIOCHEK USA CORP

Solicitation Number: CRFQ 1400 AGR2300000034
Total Bid: 68040
Response Date: 2023-06-26
Response Time: 11:37:52
Comments:

FOR INFORMATION CONTACT THE BUYER

Crystal G Husted
 (304) 558-2402
 crystal.g.husted@wv.gov

Vendor Signature X **FEIN#** **DATE**

All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Mycoplasma Meleagridis ELISA Testing Kits	252.00000	EA	270.000000	68040.00

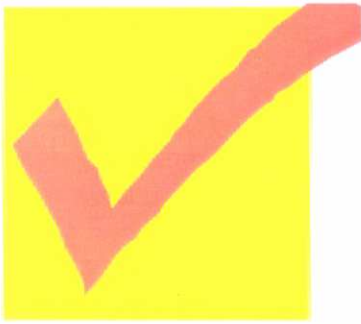
Comm Code	Manufacturer	Specification	Model #
41116126			

Commodity Line Comments: Turkey specific ELISA test

Extended Description:

Unit Price must include all shipping and handling charges

BioChek B.V.



M.meleagridis

Datapak

Mycoplasma Meleagridis Antibody
detection ELISA

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BIOCHEK Mycoplasma information pack

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VETERINARY DIAGNOSTICS

BioChek Poultry Immunoassays **Mycoplasma meleagridis Antibody Test Kit (Mm)**

Catalogue Code CK 109

Description of Test

The Mm ELISA kit will measure the amount of antibody to Mm in the serum of turkeys. Microtitre plates have been pre-coated with inactivated Mm antigen. Turkey serum samples are diluted and added to the microtitre wells where any anti- Mm antibodies present will bind and form an antigen-antibody complex. Non specific antibodies and other serum proteins are then washed away. Anti-turkey IgG labelled with the enzyme alkaline phosphatase is then added to the wells and binds to any turkey anti- Mm antibodies bound to the antigen. After another wash to remove unreacted conjugate, substrate is added in the form of pNPP chromogen. A yellow colour is developed if anti- Mm antibody is present and the intensity is directly related to the amount of anti- Mm antibody present in the sample.

Reagents provided:

1. **Mm Coated plates.** Inactivated viral antigen on microtitre plates.
2. **Conjugate reagent.** Anti-Turkey: Alkaline Phosphatase in Tris buffer with protein stabilisers, inert red dye and sodium azide preservative (0.1% w/v).
3. **Substrate tablets.** PNPP (p-Nitrophenyl Phosphate) tablets to dissolve with Substrate buffer.
4. **Substrate buffer reagent.** Diethanolamine buffer with enzyme co-factors.
5. **Stop solution.** Sodium Hydroxide in Diethanolamine buffer.
6. **Sample diluent reagent.** Phosphate buffer with protein stabilisers and sodium azide preservative (0.1% w/v).
7. **Wash buffer sachets.** Powdered Phosphate Buffered Saline with Tween.
8. **Negative control.** Specific Pathogen Free serum in Phosphate buffer with protein stabilisers and sodium azide preservative (0.1% w/v).
9. **Positive control.** Antibodies specific to Mm in Phosphate buffer with protein stabilisers and sodium azide preservative (0.1% w/v).

Materials and Equipment required (not provided with kit):

Precision Pipettes and disposable tips
8 or 12 channel pipette/repeater pipette
Plastic tubes for sample dilution
Distilled or deionised water
Microtitre Plate Reader with 405 nm filter
Microtitre Plate Washer

Warnings and Precautions:

1. Handle all reagents with care. STOP SOLUTION contains STRONG ALKALI which can be CAUSTIC. If in contact with skin or eyes, wash with copious amounts of water.
2. Treat all biological materials as potentially biohazardous, including all field samples. Decontaminate used plates and waste including washings with bleach or other strong oxidising agent before disposal.
3. NEVER pipette anything by mouth. There should be no eating, drinking or smoking in areas designated for using kit reagents and handling field samples.
4. This kit is for IN VITRO use only.
5. Strict adherence to the test protocol will lead to achieving best results.

Reagent preparation:

- 1. Substrate Reagent.** To make substrate reagent, add 1 tablet to 5.5 - 6 ml of substrate buffer and allow to mix until fully dissolved (+/- 10 minutes). The prepared reagent should be made on day of use but will be stable for one week if kept in dark at +4 °C. Drop tablets into clean container and add appropriate volume of substrate buffer.
DO NOT HANDLE TABLETS WITH BARE FINGERS
- 2. Wash Buffer.** Empty the contents of one wash buffer sachet into one litre of distilled or deionised water and allow to dissolve fully by mixing.
- 3.** All other kit components are ready to use but allow them to come to room temperature (22-27°C) before use.

Sample preparation:

- 1.** Dilute each test sample 1:100

POSITIVE AND NEGATIVE KIT CONTROLS DO NOT REQUIRE DILUTING!!

Test procedure:

- 1.** Remove Mm coated plate from sealed bag and record location of samples on template.
- 2.** Add 100 µl of negative control into wells A1 and B1.
- 3.** Add 100 µl of positive control into wells C1 and D1.
- 4.** Add 100 µl of diluted samples into the appropriate wells. Cover plate with lid and incubate at room temperature (22-27°C) for **30 minutes**.
- 5.** Aspirate contents of wells and wash 4 times with wash buffer (350µl per well). Invert plate and tap firmly on absorbent paper until no moisture is visible.
- 6.** Add 100 µl of Conjugate reagent into the appropriate wells. Cover plate with lid and incubate at room temperature (22-27°C) for **30 minutes**.
- 7.** Repeat wash procedure as in 5.
- 8.** Add 100 µl of Substrate reagent into the appropriate wells. Cover plate with lid and incubate at room temperature (22-27°C) for **15 minutes**.
- 9.** Add 100 µl of Stop solution to appropriate wells to stop reaction.
- 10.** Blank the microtitre plate reader on air and record the absorbance of controls and the samples by reading at 405 nm.

Results:

For the test result to be valid the mean negative control absorbance should read below 0.30 and the difference between the mean negative control and the mean positive control should be greater than 0.15.

Variance in lab temperatures will lead to lower or higher absorbance values. Test sample values will be relative to the control values and the test will still be valid.

The Mm positive control has been carefully standardised to represent significant amounts of antibody to Mm in turkey serum. The relative amounts of antibodies in turkey samples can then be calculated by reference to the positive control. This relationship is expressed as S/P ratio (Sample to Positive Ratio).

Interpretation of results

Samples with an S/P of 0.5 or greater contain anti-Mm antibodies and are considered POSITIVE.

1. Calculation of S/P ratio

$$\frac{\text{Mean of Test Sample} - \text{Mean of negative control}}{\text{Mean of Positive control} - \text{Mean of negative control}} = \text{S/P}$$

2. Calculation of Antibody Titre

The following equation relates the S/P of a sample at a 1: 100 dilution to an end point titre

$$\text{Log}_{10} \text{Titre} = 1.1 (\text{log}_{10} \text{S/P}) + 3.156$$

$$\text{Antilog} = \text{Titre}$$

S/P value	Titre Range	Antibody status
0.499 or less	667 or less	Negative
0.500 or greater	668 or greater	Positive

Positive samples

Additional alternative testing should be performed on any positive samples in order to obtain a confirmed positive diagnosis of Mycoplasma meleagridis within a turkey flock.

BioChek has available a software programme which can be used with the Mm kit to calculate S/P values, titres and provide general flock profiling.

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Manufacturer:
BioChek (UK) Ltd.
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London TW4 5PY

KI/CK109REV01

BioChek technical fact sheet

Following are the technical details of the BioChek flock health monitoring system.

Computer:

Hardware requirements:

IBM compatible 486 DX, 16MB RAM, hard disk, color screen 800 x 600 pixels, 100 MB available space on hard disk.

1 free serial port (in addition to mouse port)

Software requirements:

Windows: 3.11 or W 95, W98, or Windows NT

Readers:

Readers interfacing with BioChek software

SLT Spectra, TECAN sunrise, E-max, BioTech 308, 311 & 312, Dynatech MR 600 - 7000 (internal software version 3.7 required), Dynatech DIAS , Dynatech MR 5000, Dynatech MRX, Dynatech OPSYS, Multiscan +, MCC and MS, Thermo Multiscan Anthos HT, Anthos 2001.

(this list gets updated regularly, please contact us if your reader isn't on the list!!)

ELISA tests:

5 plates per kit, 2 negative and 2 positive controls per plate.

Dilution 1:500 (except ORT 1:100 and AI Multi Species 1:50), run at room temperature. Tests read at 405 NM, shelf life 1 year after manufacturing, all reagents provided. Qualitative and semi-quantitative antibody tests.

The kits are designed to cover the needs for practical serology. In general our kits will detect a positive sample 7 - 14 days after infection/vaccination and the range will comfortably cover live and inactivated vaccination titer levels.

Quality Control

In order to assure validity of obtained results BioChek has implemented the following:

Packaging:

Each plate is packed in a sealed pouch containing the microtiter plate + a pouch containing desiccant with a color indicator. When the quality of the plate is compromised the desiccant pouch color indicator will change from purple/blue to bright pink.

Certificate of analysis:

Each kit contains a certificate of analysis. The certificate of analysis contains a listing of all the components out of which the particular lot has been built + the OD values of the positive and the negative controls at QC. In addition the value of a reference control at QC is been published.

Reference control

BioChek has available an external prediluted reference control positive on most of the BioChek ELISA tests. The margin with the results of the reference control and the actual value will be published on each certificate of analysis

Key performance features BioChek M.m. antibody ELISA

Sensitivity:

Will detect antibodies to an Mm infection 3 – 8 weeks after infection

Specificity:

All our mycoplasma tests are very specific. Specificity on field flocks is > 98%. Please be aware that certain flocks may have a high percentage of false positive reactors. We recommend to confirm positive results with alternative methods.

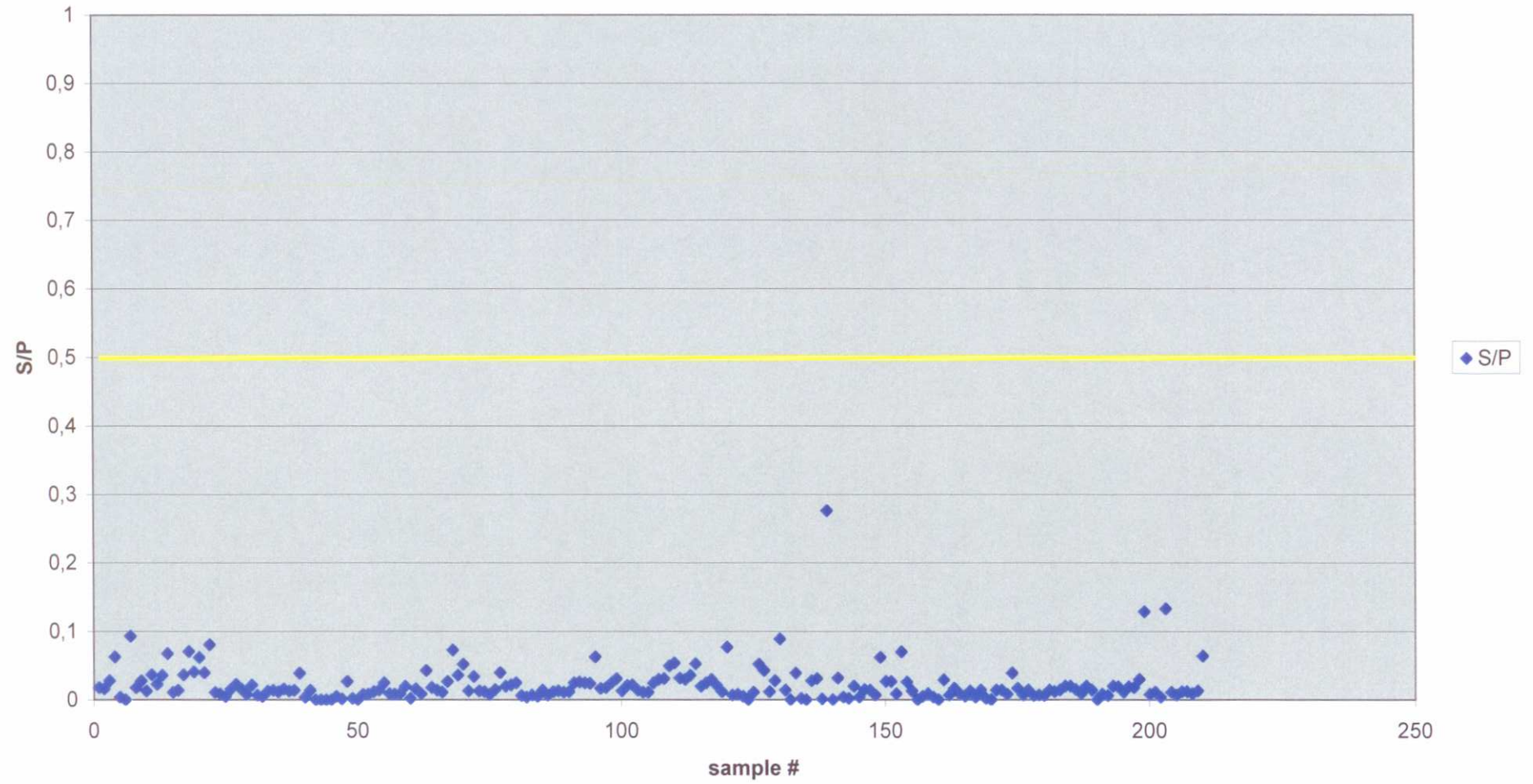
reproducibility

Plate CV's lower than 10%.

table

MM specificity panel Deventer		
Positive cutof S/P > 5		
Antisera	S/P	result
Adenovirus AGP	0,025	NEG
Fowlpox AGP	-0,004	NEG
Gumboro AGP	0,029	NEG
IBV D1466	0,047	NEG
IBV D274	0,043	NEG
IBV D3128	0,047	NEG
IBV D8880	0,056	NEG
IBV M41	0,072	NEG
ILT AGP	0,016	NEG
Mg HI	0,007	NEG
Ms HI	0,125	NEG
NDV PMV1	0,007	NEG
REO 1133	0,007	NEG
REO 2534	0,018	NEG
NDV PMV3	-0,009	NEG
ILT AGP	0,013	NEG
AE	-0,007	NEG
MM	1,340	POS
Tests done by Paul Rush, BioChek UK		

Specificity
MM negative Turkey samples



Applications of the BioChek Mm ELISA

Applications:

Most common use of the Mm ELISA is screening flocks confirming negative status of commercial Turkey flocks. When positive confirm with other method for a definite answer.