FOCUS
Diagnostics

IMPORTANT: CORRECTION NOTICE
Anaplasma phagocytophilum IFA IgM kit (IF1450M)

October 2, 2015

Dear Distributor,

The purpose of this letter is to advise you that Focus Diagnostics is providing a correction notice for the Anaplasma phagocytophilum IFA IgM (IF1450M) kit lots 26431 and 27011.

ISSUE:
Focus Diagnostics received customer complaints of IF1450M with low reactivity, which may result in a higher invalid rate. The increased variability in results is related to the combination of using the IgM Detectable Control (IF1412) lots 25757 or 26670 with the IgM Substrate Slide (IF1404) lot 25540.

Focus Diagnostics is not requesting removal of this kit from the test facility, but would like to inform you of the potential increase in invalid results.

As noted below, the risk to the patient and the general population of obtaining an invalid result is low. Other factors such as the patient's clinical symptoms and epidemiological features can provide additional information to assist in diagnosis in light of a delayed or invalid result.

RECOMMENDATION:
Focus Diagnostics is not requesting removal of the kits from the test facility. If the Detectable Control does not meet the criteria as stated in the Quality Control section of the package insert (see below), the patient test results should be considered invalid and the assay repeated. If upon repeat testing and the problem is unresolved or you experience an increase in invalid results, please contact our Technical Services department.

Page 3 of the IF1450M package insert:

QUALITY CONTROL

Each run (each time a slide, or group of slides, is processed) should include both Detectable and Non-Detectable controls.

1. The **Detectable Control** should endpoint (1+fluorescence) at 8-fold beyond the bottled dilution. However, due to differing laboratory conditions including equipment, the endpoint may range from 4 to 16-fold beyond the bottled dilution.
2. The **Non-Detectable Control** should exhibit negligible reactivity to all spots. Fluorescence that does not match the morphology and distribution of the detectable control is considered not detectable.

If controls do not exhibit these results, patient test results should be considered invalid and the assay repeated.

ACTIONS BY THE DISTRIBUTOR:

- Check to see if you have any of the identified IF1450M kit lots 26431 and/or 27011
- If your customers experience an increase in invalid results, please contact Focus Technical Services department.
- Acknowledge that you have received this notification by signing the enclosed acknowledgement form and email the form to DxTS@focusdx.com or fax back to Focus Diagnostics Technical Services at +1.562.240.6526 within 10 business days

As part of our Quality System we may audit your facility to ensure activities assigned to your facility are properly conducted. If selected, we will contact you prior to scheduling the audit.

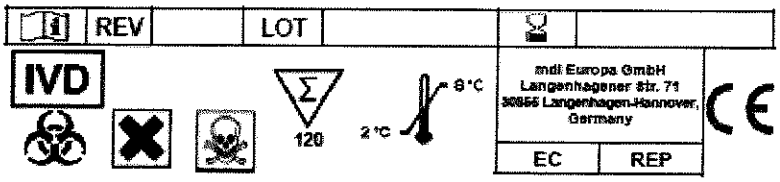
INTENDED USE:

The Focus Diagnostics Anaplasma phagocytophilum Indirect Immunofluorescence Antibody (IFA) IgM test is intended for the detection and semi-quantitation of human serum IgM class antibodies to Anaplasma phagocytophilum, as an aid in the diagnosis of Human Granulocytic Anaplasmosis (HGA).

Kit box label provided below for ease in identifying the product:

***Anaplasma phagocytophilum* IFA IgM REF IF1450M**

ENGLISH	REF	EC SYMBOL	
Substrate Slides	IF1404	Ag	
IgM Conjugate	IF0002-3	CONJ	IgM
IgM Detectable Control	IF1412	CONTROL	>
Non-Detectable Control	IF1411	CONTROL	<
IgM Pretreatment Diluent	IF0609	DIL	IgM
Mounting Medium	IF0007	REAG	MONT
Phosphate Buffered Saline (PBS) Powder	IF0005	BUF	



RISK TO HEALTH:

Diagnosis of HGA is usually made on the basis of both clinical and epidemiological features. A delayed result due to an invalid assay should not prevent any treatment.

Typically treatment is started empirically with doxycycline for suspected cases and it is not necessary or recommended to wait for the test results.

Even if the test result is delayed the patient will likely be recovered or much improved by the time the test result is obtained. Therefore, any delayed test results will likely not have much patient impact if the test result is positive. If delayed results are negative for anaplasma, there is likely minor patient impact as well, as treatment with doxycycline is indicated for other closely related infections such as Erlichia.

BACKGROUND:

The indirect immunofluorescent antibody (IFA) assay is a two stage "sandwich" procedure. In the first stage, the patient serum is diluted in IgM Pretreatment Diluent. The diluted serum is placed on the slide in contact with the substrate, and incubated. Following incubation, the slide is washed in PBS, which removes unbound serum antibodies. In the second stage, each antigen well is overlaid with fluorescein-labeled antibody to human IgM. The slide is incubated allowing antigen antibody complexes to react with the fluorescein-labeled anti-human IgM. After the slide is washed, dried, and mounted, it is examined using fluorescence microscopy. Positive reactions appear as apple-green fluorescence of the morulae. Semi-quantitative endpoint titers are obtained by testing serial dilutions of positive specimens.

Please accept our apologies for any inconvenience this may have caused. If you have any questions or require additional information, please contact our Technical Services department at +1.562.240.6550, between the hours of 7am to 5pm (PST) or send an email to DxTS@focusdx.com.

Sincerely,

Valerie Cimmarusti

Valerie A. Cimmarusti
Vice President, Quality and Regulatory

Attachments: Acknowledgement Form