

FTD-60.4 Neuro 9
Potential false positive while using FTD-60.4 Neuro 9 kit

Dear customers,

We kindly ask you to urgently review the following communication:

Details on affected product:

Our records indicate that your facility may have received the following product:

Table 1 Affected products

| Kit name | Catalog Number | Siemens Material Number (SMN) | Lot Number | Manufacturing /1 st Distribution Date (DD/MM/YYYY) |
|-------------|-----------------------------|-------------------------------|------------|---|
| FTD Neuro 9 | FTD-60.4-32, FTD-60.4-64 | 10921800 10921801 | All lots | 25/05/2016 |

Reason for the Field Safety Notification:

The purpose of this communication is to inform you of an issue affecting the product indicated above and to provide instructions on actions that your laboratory must take.

After internal investigation, Fast Track Diagnostics (FTD) has observed that nonspecific low positive signals may be generated for negative samples randomly while using the kit FTD-60.4 Neuro 9. Based on initial analysis of the available data, negative samples may be incorrectly reported as low positive. For an estimation of the rate of nonspecific signals that may be observed, please refer to table 2. Please note that this rate of false positive signals may vary from one laboratory to another.

Table 2 Potential rate of nonspecific signals per pathogen

| Pathogen | Potential rate of nonspecific signals |
|-----------------------|---------------------------------------|
| Epstein-barr virus | 8,2% |
| human cytomegalovirus | 2,3% |
| human adenovirus | 6,4% |

Risk to Health:

For the FTD-60.4 kit, nonspecific low positive signals can lead to false positive detection of human cytomegalovirus (HCMV), Epstein-barr virus (EBV) and human adenovirus (HAdV), which may impact treatment considerations. Depending on the pathogen, clinical context and treatment, results would be used in conjunction with clinical presentation and results of other testing.

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Actions to be taken by the user:

1. Fast Track Diagnostics recommends a review of previously generated results for patients currently under treatment for HAdV, HCMV, and EBV as follows:

For any suspicious case that produces a low positive result, Fast Track Diagnostics recommends confirmatory testing using another detection technique.

Low positive signals are defined as positive amplification with cycle threshold (Ct) values indicated in Table 3, for users using these products in combination with the easyMag[®] and Applied Biosystems[®] 7500 (Thermo Fisher Scientific) instruments:

Table 3: Ct values for nonspecific low positive signals

| Pathogen | Ct value* |
|----------|-----------|
| HAdV | >35 |
| HCMV | >36.5 |
| EBV | >34 |

* Ct values obtained from the validated cyclers Applied Biosystems[®] 7500

2. If you have received any complaint or report of illness or adverse events associated with FTD-60.4, immediately contact FTD at: support@fast-trackdiagnostics.com.
3. Please complete and return the Field Correction Effectiveness Check Form attached to this letter for the 10th of July 2019.

Customers not running the above-mentioned instruments should review their internal validation files and assess the need for further action.

This issue remains under investigation at FTD and additional information or updates will be provided as they become available.

Please review this letter with your medical advisor and retain this letter with your laboratory records and forward this letter to those who may have received this product.

If you have any questions, please contact FTD at: support@fast-trackdiagnostics.com.

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FIELD CORRECTION EFFECTIVENESS CHECK

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This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-05, dated June 2019 regarding "Potential false positive while using FTD-60.4 Neuro 9 kit". Please read each statement and indicate the appropriate answer.

Email this completed form to the email address provided at the bottom of this page, by the **10th of July 2019**.

- 1. I have read and understood the Field Safety Notice instructions provided in this letter. Yes No

- 2. I am a distributor of the affected products AND my customers received FTD-60.4 Yes No

If the answer to statement 2 above is yes, please confirm that you forward the relevant information to your impacted customers. Yes No

Name of person completing questionnaire:

Title:

Institution:

Street:

City:

State:

Phone:

Country:

Signature
and date

Please send a scanned copy of the completed form via email to vigilance@fast-trackdiagnostics.com. If you have any questions, contact a Fast Track Diagnostics support representative.