

**FTD-60.4 Neuro 9
 Potential false positive while using FTD-60.4 Neuro 9 kit –
 Updated Information**

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 Notification:

Following additional investigation, Fast Track Diagnostics has revised the advice for product users, as specified in “Actions to be taken by the user”, below.

Please make note that, to ensure optimal coverage, the indicated Ct cut-off values have been modified for both human cytomegalovirus (HCMV) and human adenovirus (HAdV).

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.

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:

**FTD-60.4 Neuro 9
Potential false positive while using FTD-60.4 Neuro 9 kit –
*Updated Information***

NOTE: Recommended Ct thresholds have been revised since the initial notification in June:

For any suspicious case that produced 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 2, for users using these products in combination with the easyMag® and Applied Biosystems® 7500 (Thermo Fisher Scientific) instruments.

Table 2: Ct values for nonspecific low positive signals

Pathogen	Ct value*
HAdV	>34
HCMV	>34
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 22th of August 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.

Fast Track Diagnostics assays are manufactured by Fast Track Diagnostics S.à.r.l. and Fast Track Diagnostics is a registered trademark of Fast Track Diagnostics Ltd.

All other trademarks are the property of their respective owners.

FIELD CORRECTION EFFECTIVENESS CHECK

Potential false positive while using FTD-60.4 Neuro 9 kit, Update August 2019

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-05, dated August 2019 regarding "Potential false positive while using FTD-60.4 Neuro 9 kit, Update August 2019". 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 **22th of August 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.

**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.

Actions to be taken by the user:

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

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.

Fast Track Diagnostics assays are manufactured by Fast Track Diagnostics S.à.r.l. and Fast Track Diagnostics is a registered trademark of Fast Track Diagnostics Ltd.

All other trademarks are the property of their respective owners.

FIELD CORRECTION EFFECTIVENESS CHECK

Potential false positive while using FTD-60.4 Neuro 9 kit

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 technical support representative.