

February 2024

Important Notice: *therascreen*[®] MGMT Pyro Kit LOT shows no signals

Dear valued customer,

We would like to inform you that we have identified an issue with one specific LOT of the Methylated Control DNA LOT 175028686 delivered with the *therascreen* MGMT Pyro[®] Kit (48) LOTs listed in the table below. We received feedback from the market that methylated control DNA LOT 175028686 is not showing any signals when using Pyrosequencing technology on the PyroMark[®] Q24 System.

According to our records, you have received at least one of the affected kit LOTs, including the affected methylated control DNA LOT 175028686.

Cat. No.	Kit	LOT
971061	<i>therascreen</i> MGMT Pyro Kit (48)	175030723
971061	<i>therascreen</i> MGMT Pyro Kit (48)	175034299

Description of the issue

We have detected that methylated control DNA LOT 175028686 cannot be properly amplified during the PCR amplification step and thus is not showing any signals when using Pyrosequencing technology on the PyroMark Q24 System. This issue is limited to this one specific LOT of methylated control DNA (175028686) and does not affect other samples.

Potential risk associated with this issue

Non-functioning positive control DNA could cause delayed diagnosis since sample testing would have to be repeated.

Actions to be taken by the customer/user

- Kindly forward this information to all users of the above-mentioned products in your organization. If you are not the end-user, please forward it to the end-user on our behalf.
- Do not use the remaining stock of *therascreen* MGMT Pyro Kit (48) LOTs 175030723 and 175034299. Dispose of it immediately in accordance to your national and local safety and environmental regulations.
- To obtain a free-of-charge replacement, please contact your local QIAGEN Technical Service.

Actions for Commercial Partners:

- Forward this Important Notice to your customers.

Please do not hesitate to contact the QIAGEN Technical Services team at support.qiagen.com if you have any further questions about the above points. To find contact information for QIAGEN Subsidiaries, please visit

www.qiagen.com/subsidiaries.



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We apologize for any inconvenience this may cause, and thank you in advance for your assistance.

If you have further questions, please contact your local QIAGEN representative or contact our Technical Support Center at www.qiagen.com/support/technical-support

Sincerely,

Your QIAGEN Team
www.qiagen.com

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