

Quality Information

Product Notification
Phadia™ 200

Purpose:

Quality Information about Product Notification, PN2022-08

Distribution:

Australia, Austria, Bahrain, Belgium, Belarus, Bosnia-Herzegovina, Botswana, Bolivia, Brazil, Chile, Colombia, Croatia, Czech Republic, Denmark, Djibouti, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong, India, Japan, South Korea, Latvia, Lithuania, Malaysia, Mauritius, Netherland Antilles, Panama, Poland, Portugal, Romania, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Ukraine, United Arab Emirates, United Kingdom and Uzbekistan

Product:

Product	Material number	Affected Model/Lot/Serial Number
Phadia 200	12-4300-00	All serial numbers

Description of the problem:

An issue has been found when the Phadia 200 Software has the setting “Automatic approval by each available result” and the Curve Control (CC) for an EliA assay run is not OK. This combination can lead to samples being approved without an OK Curve Control for the assay run.

Curve Controls, CC1 and CC2, are used for each EliA assay run and loaded as number 1 and 2 in the Immunoreaction wheel. After the CC’s either samples or Quality Controls are loaded as number 3, 4 and so on up to 48.

When loading samples in the Phadia 200 instrument Immunoreaction wheel, it is performed in the following order:

Position 1: CC 1

Position 2: CC 2

Position 3: Sample 1

Position 4: Sample 2

Position 5: Sample 3

Position 6: Sample 4

Position 7: Sample 5

Position 8: Sample 6

...and so on...



When the Phadia 200 Software reports the results, it is performed in the following order:

Position 4: Sample 2

Position 3: Sample 1

Position 2: CC 2

Position 1: CC 1

Position 8: Sample 6

Position 7: Sample 5

Position 6: Sample 4

Position 5: Sample 3

...and so on...

If the Curve Control is not OK the samples should not be approved, however since the Phadia 200 Software reports position 3 and 4 before position 1 and 2 these two samples will be approved if the Phadia 200 Software has the setting “Automatic approval by each available result”.

If Curve Controls, e.g an assay is run with more than one method, or Quality Controls are loaded in position 3 and 4 there will be no impact on the following samples as no test results will be reported. The same applies if a calibration curve is performed in the assay.

This issue affects EliA assays run on the Phadia 200 instrument. EliA assay affected by this issue is listed in Appendix 1. ImmunoCAP assays or the other Phadia instruments are not affected by this issue.

It is not likely that this issue would lead to false positive or false negative EliA results being reported and there is no indication that this have occurred at customers. The probability for serious injury due to false EliA results caused by this issue is estimated to be not likely.



Actions- Customer/User:

- Identify if your Phadia 200 instrument is affected by the issue according to the Instruction in Appendix II.
 - If you need help changing the settings, please contact the Local Service Organization
- Determine if retesting of affected samples is needed according to your internal operating procedures.
- Please fill in Acknowledgement Form in the Customer reply form PN2022-08, and return the response to the contact person as described.

Actions- Commercial organization

- Send the Commercial organization initial report to Global QA, see page 4, as a confirmation that the information has been received.
- Schedule a software update for the customers when it is available.
- Send the commercial organization final report to Global QA, see page 5, when communication with customers has been performed.

Actions – Manufacturer Site

- Provide updated software
- A CAPA, CA22-00061 have been initiated to prevent this from reoccurring.

Transmission of this Notification:

Please ensure that this notice is shared with anyone who needs to be made aware within your organization, or to any organization on which this notification potentially has an impact. We apologize for any inconvenience this event may cause. If you have any questions, please contact us.

Contact/Questions:

vigilance.idd@thermofisher.com



Commercial organization initial report

Phadia™ 200

I hereby acknowledge that we have received this QI and PN2022-08:

Yes

Date: _____

Signature: _____

(Please print name): _____

Country/countries: _____

E-mail a signed copy to:

vigilance.idd@thermofisher.com



Commercial organization final report

Phadia™ 200

I hereby confirm that the following has been performed:

- Informed affected customer about the content in PN2022-08.

Yes

No

If No, reason:

- Customer response rate 100 %

Yes

No

If No, give actual response rate:

Evidence of a minimum of three faith efforts to contact the customers is saved.

- Sent required information to the authority.

Yes

No

If No, reason:

Evidence of communication with authorities is saved.

Date: _____

Signature: _____

(Please print name): _____

Country/countries: _____

E-mail a signed copy to:

vigilance.idd@thermofisher.com



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Appendix 1 – Tests that may be affected by QA2022-08

EliA RNP70	EliA CENP
EliA CCP	EliA dsDNA
EliA GBM	EliA b2 Glycoprotein 1 IgG
EliA Cardiolipin IgG	EliA Celikey IgG
EliA Jo-1	EliA La
EliA U1RNP	EliA Ro
EliA Ro60	EliA Rib P
EliA RF IgM	EliA GliadinDP IgG
EliA CTD Screen	EliA PR3S
EliA Ro52	EliA MPOS
EliA PM-Scl	EliA Fibrillarlin
EliA Mi-2	EliA SmDP
EliA PCNA	EliA ssDNA
EliA ASCA IgG	EliA anti-TPO
EliA anti-TG	EliA M2
EliA Scl-70s	EliA RF IgG
EliA RNA Pol III	EliA Parietal Cell
EliA Intrinsic Factor	EliA SymphonyS
EliA DFS70	EliA SmDP-S
EliA LKM-1	EliA Gliadin IgG
EliA Celikey IgA	EliA Cardiolipin IgA
EliA b2 Glycoprotein 1 IgA	EliA Calprotectin 2
EliA RF IgA	EliA CCP IgA
EliA ASCA IgA	EliA b2 Glycoprotein 1 IgM
EliA Cardiolipin IgM	EliA Anti-IgA



Document name Appendix 1 - Tests that may be affected by QA2022-08
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Appendix II QA2022-08

About this document

This document concerns Phadia™ 200 instruments that run the EliA™ technology. It describes how to

- identify if a Phadia 200 instrument is affected by the issue described in QA2022-08
- change the settings to prevent the issue
- identify historical runs that have been affected by the issue

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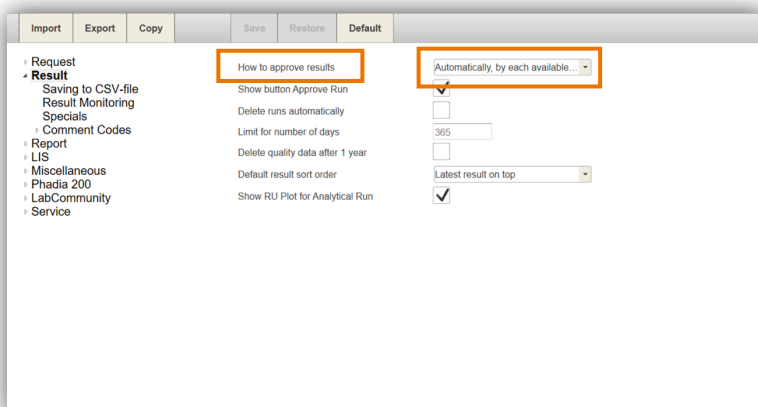


1 Prerequisites

The user must have the advanced user role **Settings viewer** (to identify results) or **Settings writer** (to edit the settings).

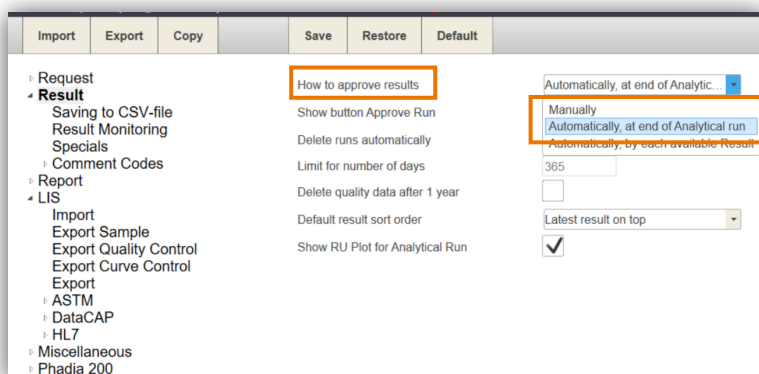
2 How to identify if an instrument is affected

1. In **Phadia Prime**, go to **Settings > Result**.
2. Check if the setting **How to approve results** is set to **Automatically, by each available Result**.



3 How to change the settings

1. In **Phadia Prime**, go to **Settings > Result**.
2. Make sure that the setting **How to approve results** is set to **Automatically, at end of Analytical run** or **Manually**.



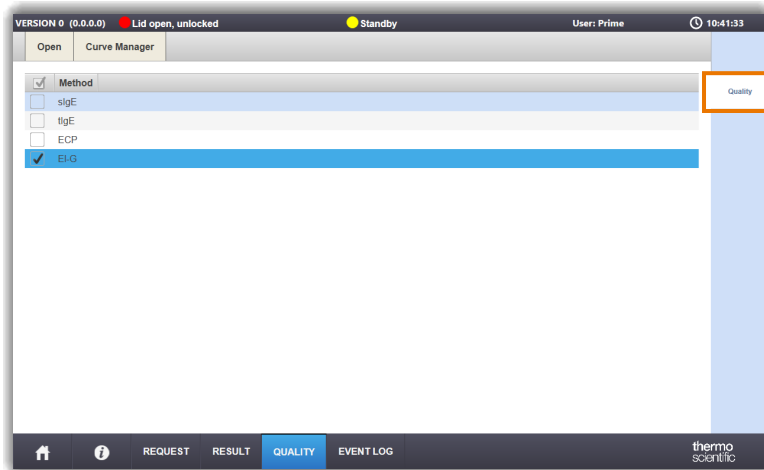
3. Press **Save**.



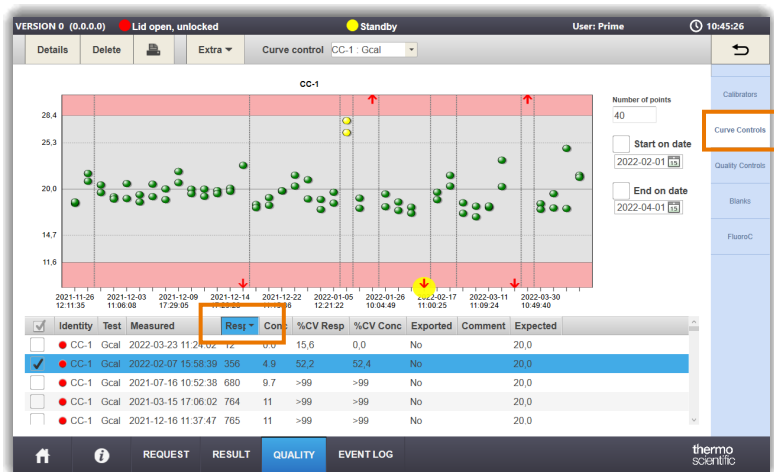
4 How to find any affected EliA results in historical runs

IMPORTANT: Do the steps below for each EliA method that is used on the instrument. ImmunoCAP is not affected.

1. Go to the **Quality** window, then select an EliA method. Press **Open**.



2. Select **Curve Controls**. For each Curve Control, press **Resp** to sort the results in numerical order.



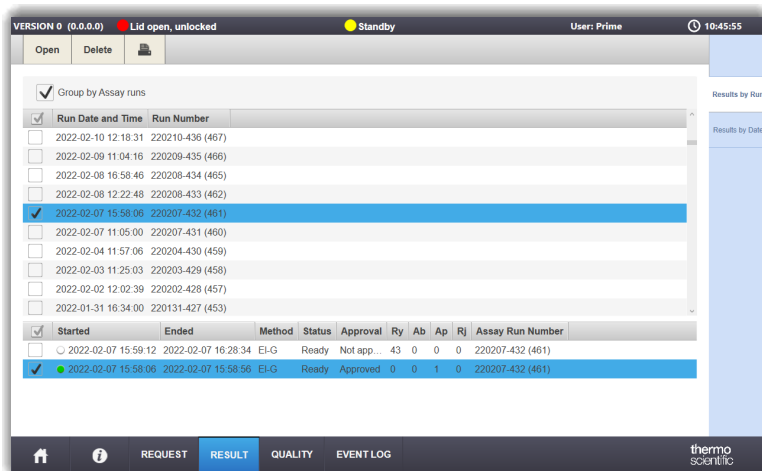
3. For each failed result, note the date.

NOTE: Look at the lowest value, then scroll to the highest value.

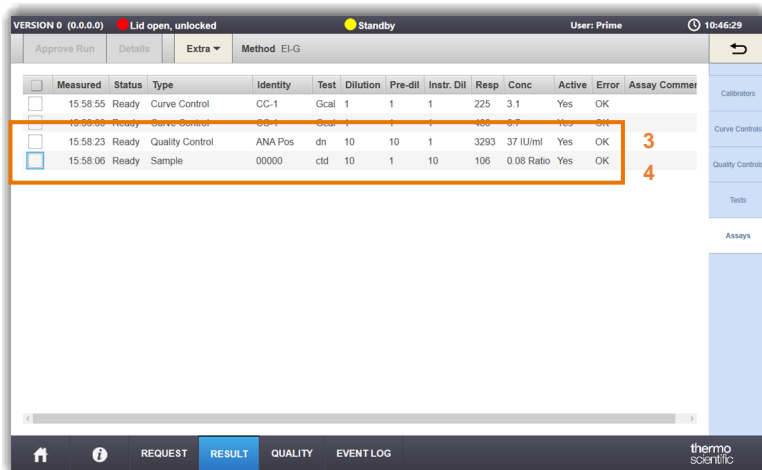
4. Go to the **Result** window.



5. Select the noted date, then the analytical run with the earliest time. Press **Open**.



6. Look at the samples, If a sample was run in position 3 or 4, it is affected by this issue.



Document name Appendix II - Change settings QA2022-08
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