QC SEROLOGY INVESTIGATION PMM-QC-689

NRL is:

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- **A World Health Organisation (WHO) Collaborating Centre for Diagnostics and Laboratory Support for HIV and AIDS and Other Blood-borne Infections.**

Report prepared by Joe Vincini

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NRL Science of Quality
4th Floor Healy Building
41 Victoria Parade
FITZROY VICTORIA 3065
AUSTRALIA
T. +61 3 9418 1111
F. +61 3 9418 1155
www.nrl.gov.au
A.C.N. 004 705 640
NRL is a WHO Collaborating Centre

1 Introduction

NRL was contacted by Abbott Laboratories, Australia, regarding Participant 128 having reported that there was evidence to suggest there was greater variation observed for HEPR:DM17216 since the introduction of the ARCHITECT anti-HBs version 3.

2 Findings

Figure 1:- All lab data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 by Participant.

Figure 2:- All lab data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 by Reagent Lot.

Figure 3:- Comparison of Participant 825 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from December 2018 to February 2019 by reagent lot.

Figure 4:- Participant 825 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM17155 from November 2018 to December 2018 by reagent lot.

Figure 5:- Participant 825 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from December 2018 to February 2019 by reagent lot.

Figure 6:- Participant 825 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM17155 and DM18210 from November 2018 to February 2019 by reagent lot.

Figure 7:- Participant 30 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by reagent lot.

Figure 8:- Participant 30 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by instrument.

Figure 9:- Participant 30 data for Abbott ARCHITECT Anti-HCV positive kit control from January 2018 to February 2019 by instrument.

Figure 10:- Participant 46 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 by reagent lot.

Figure 11:- Participant 46 data for Abbott ARCHITECT Anti-HCV Positive kit control by reagent lot.

Figure 12:- Participant 83 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by reagent lot.

Figure 13:- Participant 83 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by instrument.

Figure 14:- Participant 83 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by operator.

Figure 15:- Participant 365 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by reagent lot.

Figure 16:- Participant 365 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by instrument.

Figure 17:- Participant 365 data for Abbott ARCHITECT Anti-HCV Positive kit control from January 2018 to February 2019 by reagent lot.

Figure 18:- Participant 382 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 by reagent lot.

Figure 19:- Participant 382 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from January 2018 to February 2019 instrument.

Figure 20:- Participant 382 data for Abbott ARCHITECT Anti-HCV Positive kit control from January 2018 to February 2019 by reagent lot.

Figure 21:- Participant 148 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM17155 from November 2018 to February 2019 by reagent lot.

Figure 22:- Participant 148 data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 from November 2018 to February 2019 by reagent lot.

Figure 23:- Participant 148 data for Abbott ARCHITECT Anti-HCV Positive kit control from November 2018 to February 2019 by reagent lot.

Table 1:- All lab data for Abbott ARCHITECT Anti-HCV QConnect BLUE:DM18210 by Participant.

3 Discussion

When investigating Participant 825 data for variability of QConnect Blue:DM18210, the data from previous QConnect lot numbers used by Participant 825 and data from across the peer group was examined to establish if any common trends were evident.

Figures 1, 2 and 3 illustrate Participant 825 data in comparison to peer group data for QConnect Blue:DM18210. Peer group data showed a number of participants with large spread of data across most of the reagent lots in use. Predominately the peer group data was within QConnect Limits (2.20- 3.50 S/Co) with few out lyres, most evident of which was identified in Participant 83 and will be investigated further in this report.

Regarding Participant 825, the variability in data was identified in early January 2019. Looking back at data including the previous QConnect lot number, Blue:DM17155, there was some variation seen across both QC lots within one reagent lot, all data was within QConnect Limits. In early January 2019 (14th Jan.) the variation in data increases significantly. In the data previous to January 14th the largest daily data variation was approximately 0.37 S/Co on the 20th December 2018. Post January 14th 2019 the largest daily data variation was approximately 0.77 S/Co on January 14th (figures 4, 5 and 6).
NRL confirmed with Participant 825 there was only one Abbott ARCHITECT instrument in use at the facility and no kit control data was provided for comparison.

The overall results from all participants in the peer group indicated a total %CV of 9.40 (Table 1). Participant 825 reported a %CV of just below the total of 8.94. Overall the participants had a %CV of between 0-10, including participant 825. Only one participant had a %CV above 10 (participant 46). The data for Participant 46 was investigated further. Participant 46 has 16 data points entered for QConnect Blue:DM18210, two data points fall below QConnect Limits and only one reagent lot was in use. Participant 46 provided positive kit control data for comparison, figure 9 shows that the positive kit control followed the same pattern of variability as QConnect Blue:DM18210.

When investigating possible causes for Participant 825 data variation, peer group data was looked at on an individual participant level to see if the same variation could be

identified in any other participant. Five other participants were showing similar data variation, all to a lesser extent than Participant 825, and 2 showed data outside QConnect Limits.

Participants 30, 365 and 382 (Figures 7, 8, 9, 15, 16, 17, 18, 19 and 20) all showed the same variation pattern of rises and drops as seen in Participant 825. These three participants provided positive kit control data for comparison and as can be seen in figures 9, 17 and 20, all show the same pattern of variation seen in the QConnect control for these participants. Unlike Participant 825, these three participants were running two or more Abbott ARCHITECT instruments and the variation can be attributed to a variation between the multiple instruments (Figures 7B, 10 and 13). Variation between instruments can have a number of contributing causes ranging from Instrument maintenance schedule and needs, different calibration dates and lot numbers in use, different reagents on board, different operators to different locations in the laboratory.

Participant 83 data, figures 12, 13 and 14, show six data points out of range grouped together over a four day period within a single reagent lot. Five of the six data points are from a single instrument and no single operator is common for all data. The participant has not given a reason for these data spikes in EDCNet and current data is within QConnect limits.

Figures 21 and 22 illustrate Participant 148 data for Abbott ARCHITECT Anti-HCV QConnect Blue:DM17155 and DM18210 respectively. The data had a wide range and shows similar amounts of variation as see in Participant 825. There were approximately 100 less data points entered for Participant 148 than Participant 825 therefore the variation initially appear less obvious. However Participant 148 provided Positive kit control data (figure 23) and this data confirms the same variation is present. Participant 148 had only one Abbott ARCHITECT instrument in use on which the variation was seen across and within multiple reagent lots and on two QConnect control lot numbers.

Participants 825 and 148 showed high variation both across and within reagent and EQC lots, and positive kit control in the case of Participant 148. Participant 825 did not provide any kit control data for investigation. The cause of similar variation seen in Participants 30, 365 and 382 was concluded to be due to the differences between instrument performance, both Participant 825 and 148 were running one instrument so this can be ruled out as a factor in their case. It is likely that a combination of instrument precision, maintenance, calibration and possible sample preparation and storage are the cause of variation.

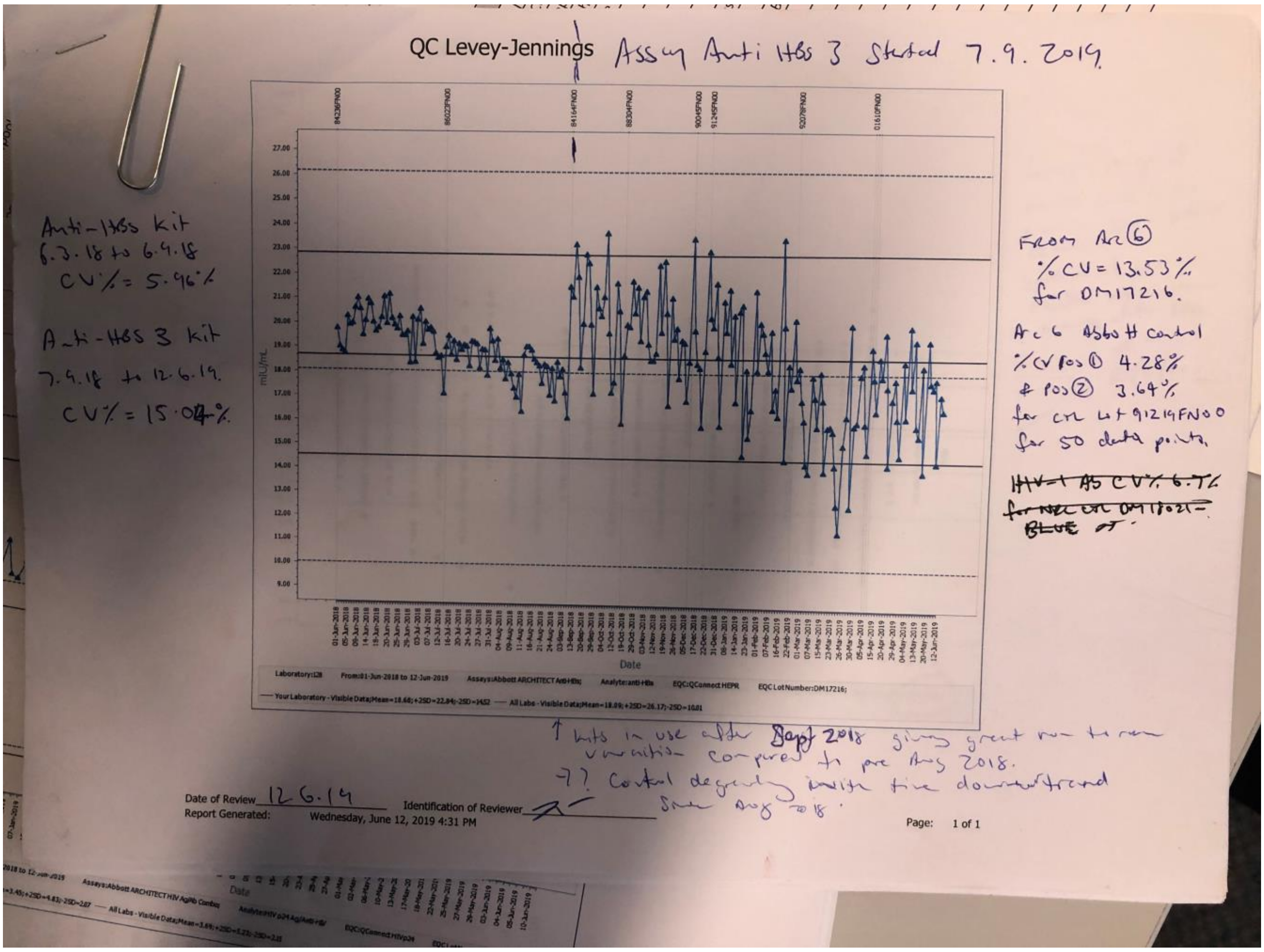
4 Recommendations

NRL requests Participant 825 provides kit control data for the period QConnect Blue:DM18210 was in use for comparison. Along with the time of day both the QConnect and kit control samples were tested.

NRL requests calibration and maintenance data from both Participants 825 and 148 for the time period from December 2018 until the end of February 2019. The limited amount of data for Participant 46 limits an investigation at this time, NRL recommends monitoring this participant to see if the current %CV and variability improves.

NRL has requested participant 83 look into the instrument and operational logs corresponding to the out of range data spikes to identify any possible causes and corrective actions.

NRL recommends that Participants 30, 365 and 382 make their operators aware of the instrument differences and consider monitoring the instruments data individually and combined. This will better highlight any possible instrument bias or issues.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Anti-HBs 3 kit 7.9.18 to 12.6.19. CV% = 15.04%
FROM Arc ⑥ %CV = 13.53% for OM17216.
Arc 6 AbsoH control %CV Pos ① 4.28% & Pos ② 3.64% for ctrl lot 91219FN00 for 50 data points.
mIU/mL
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Identification of Reviewer
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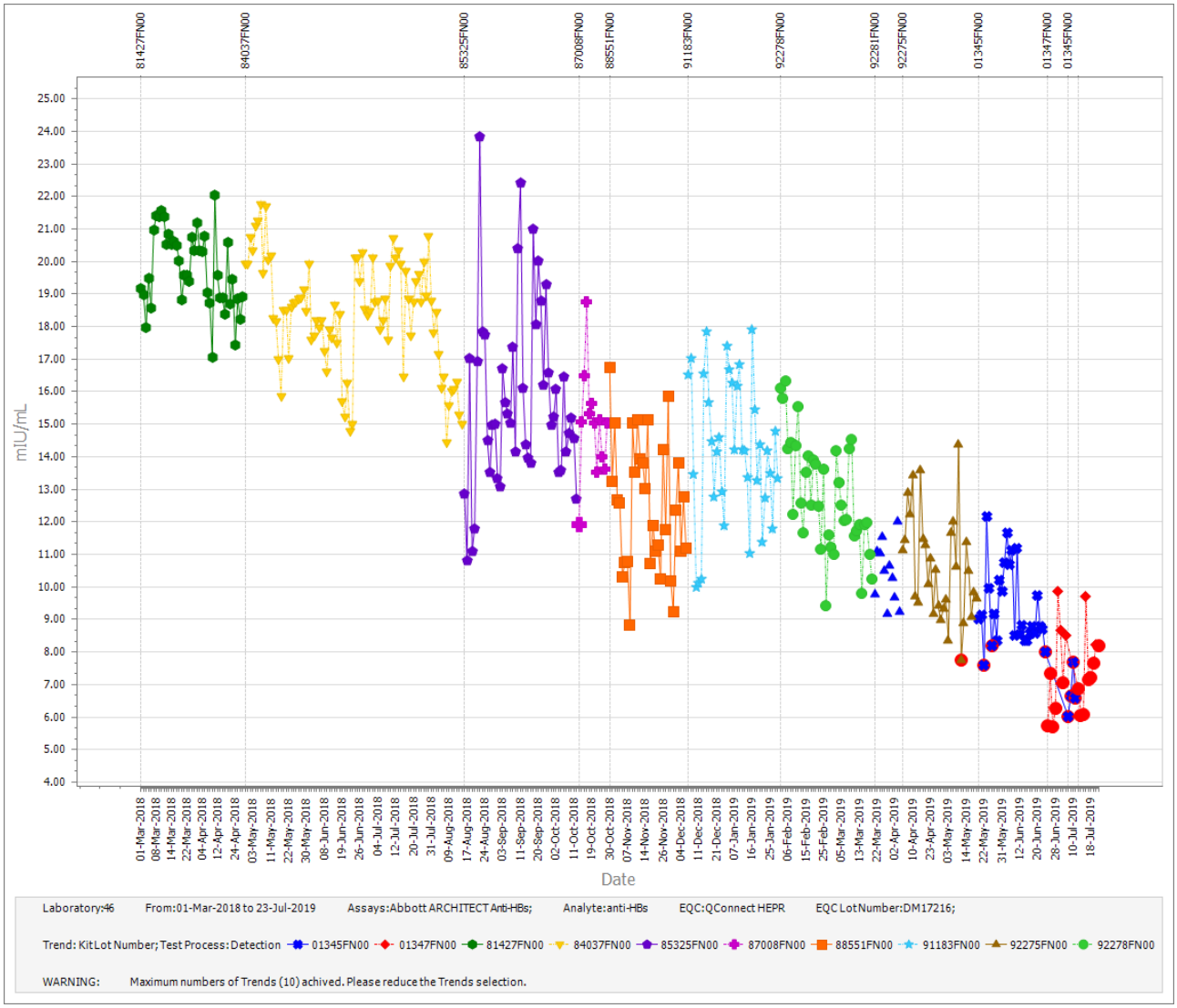
Page: 1 of 1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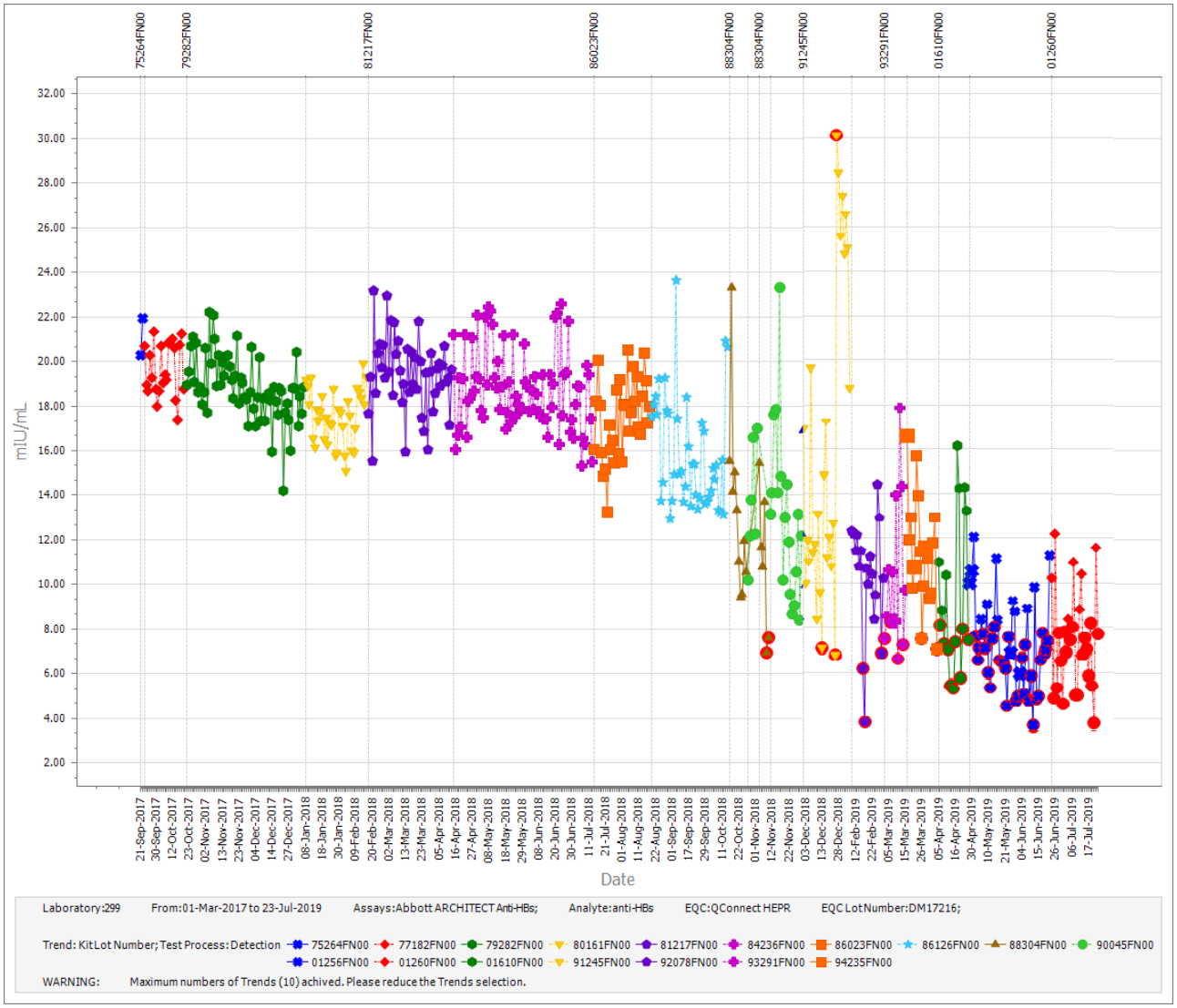
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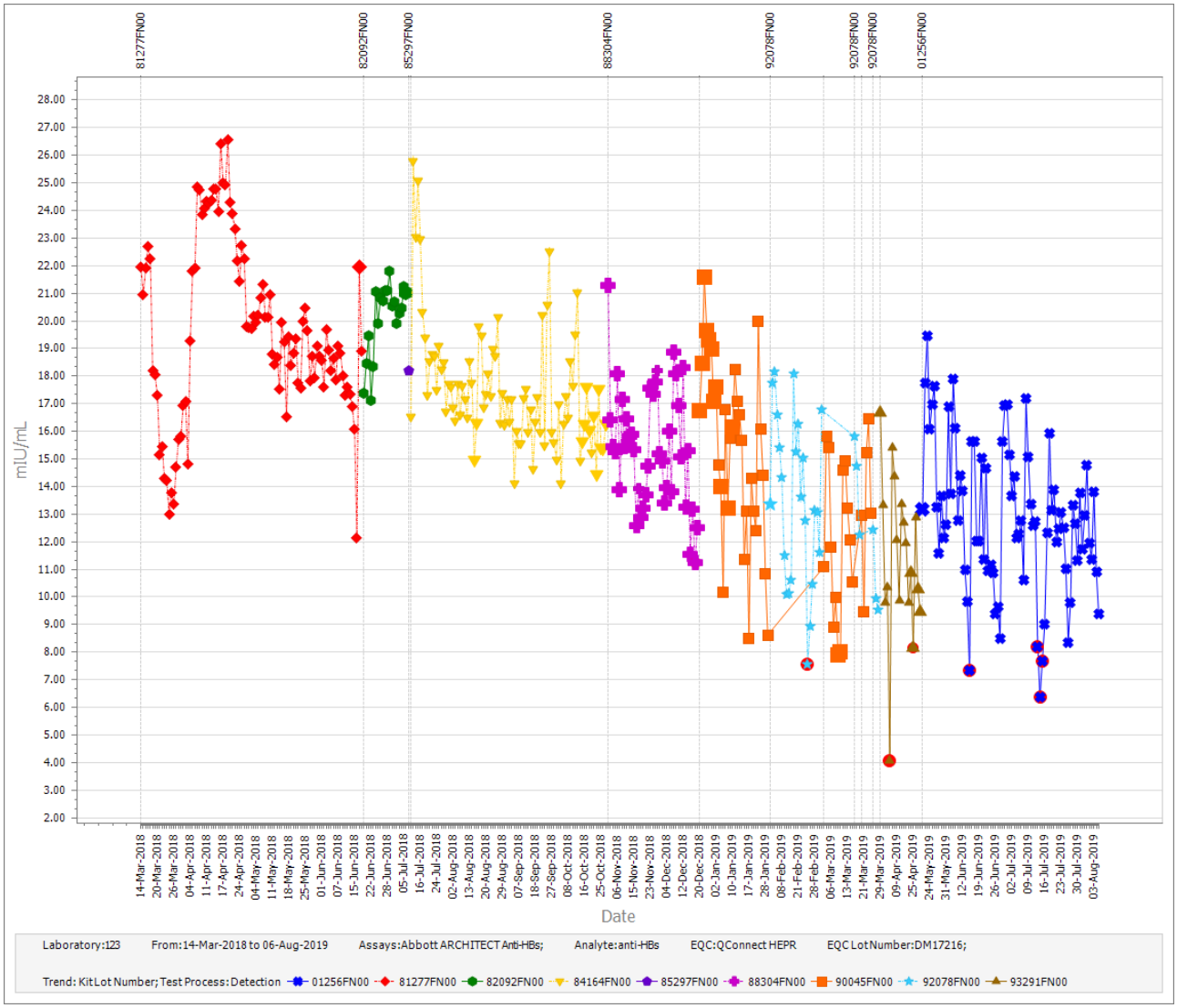
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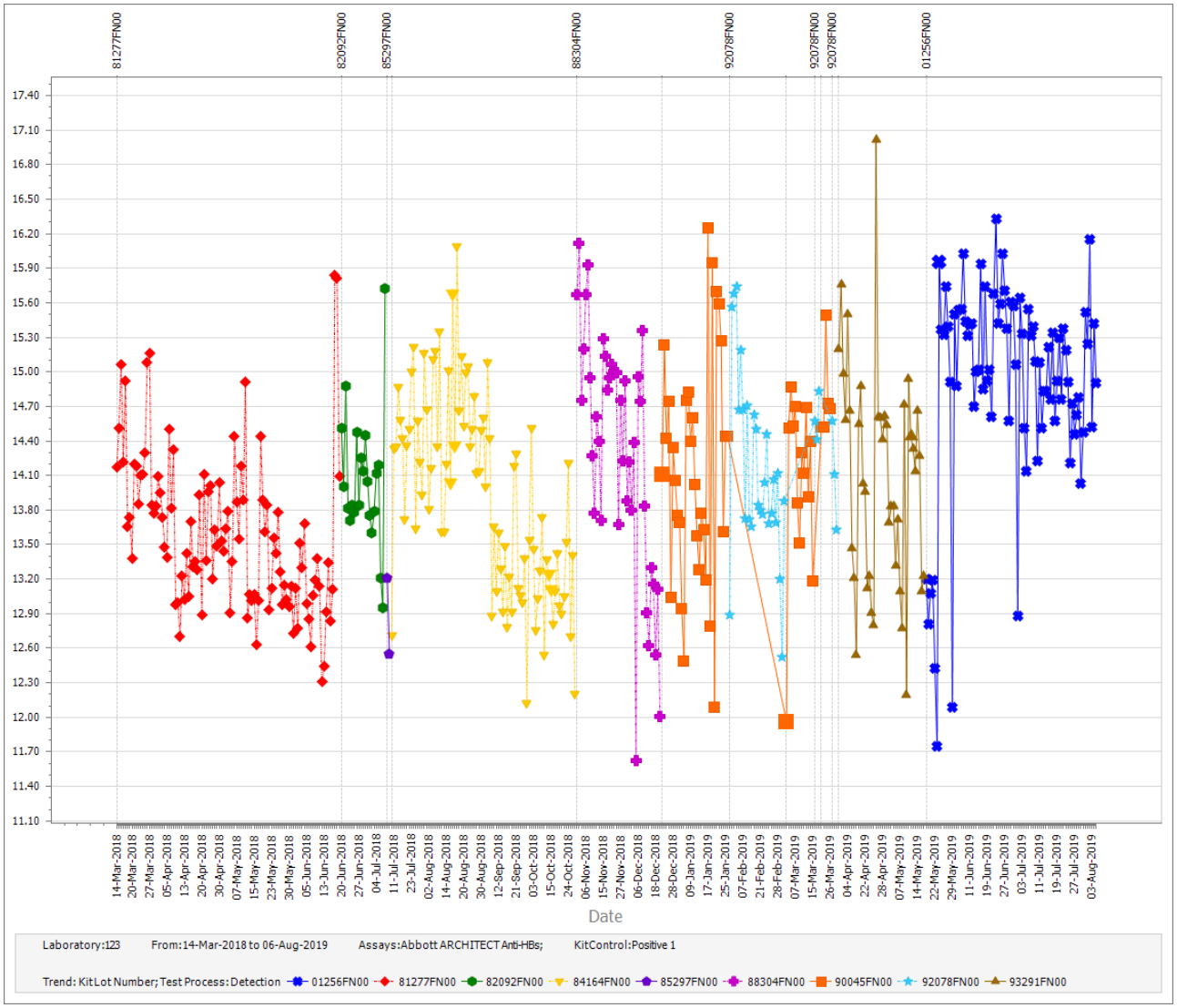
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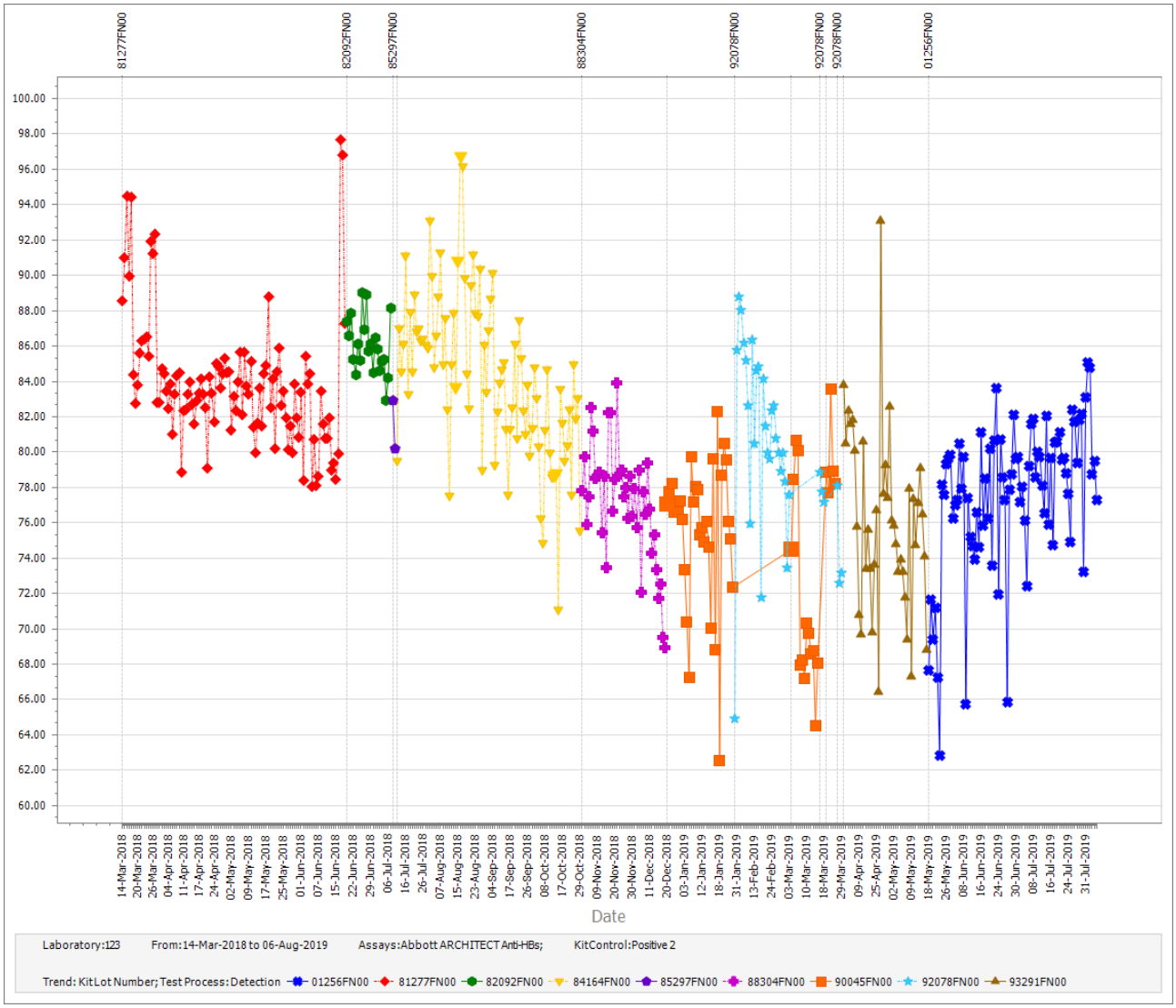
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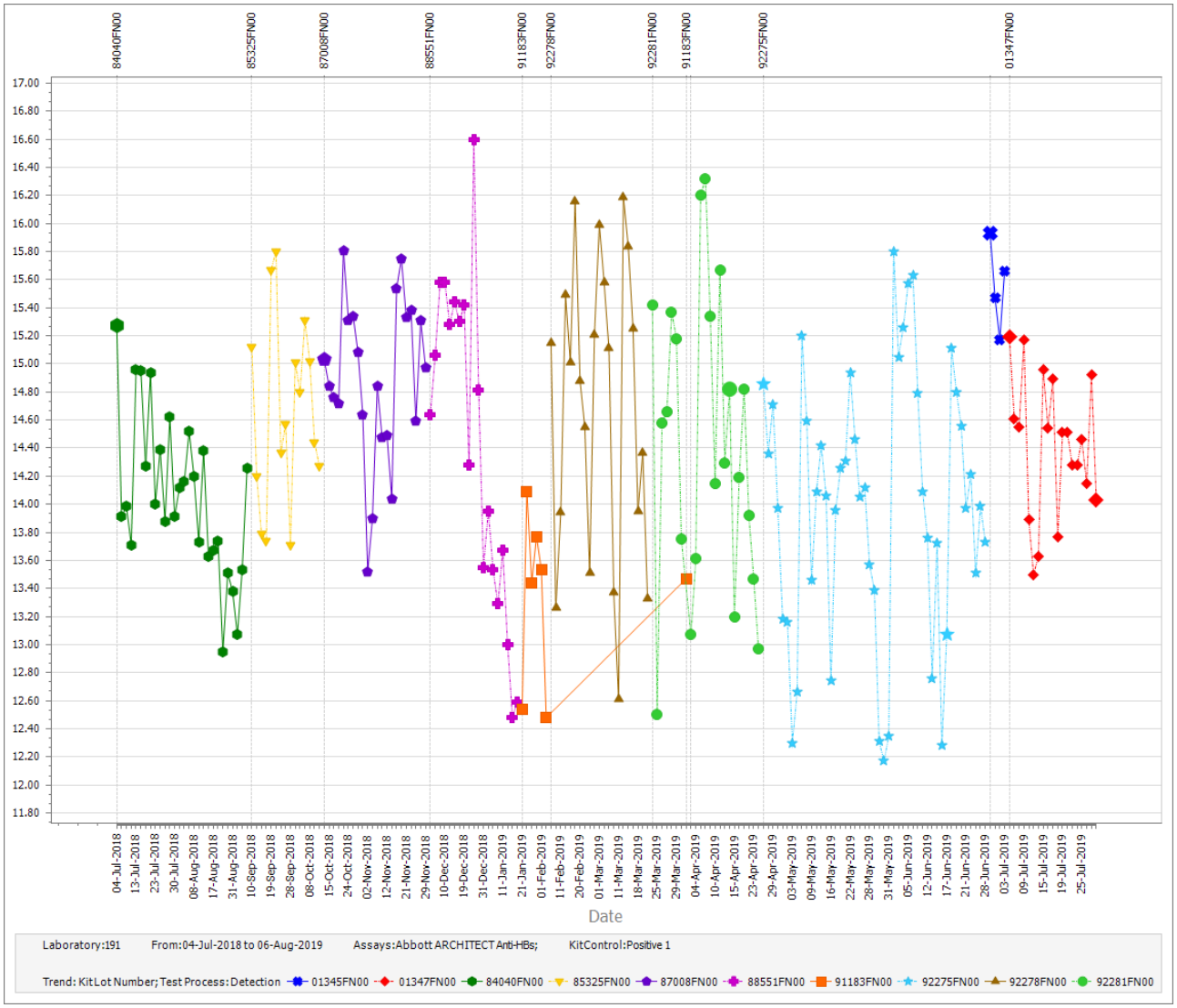
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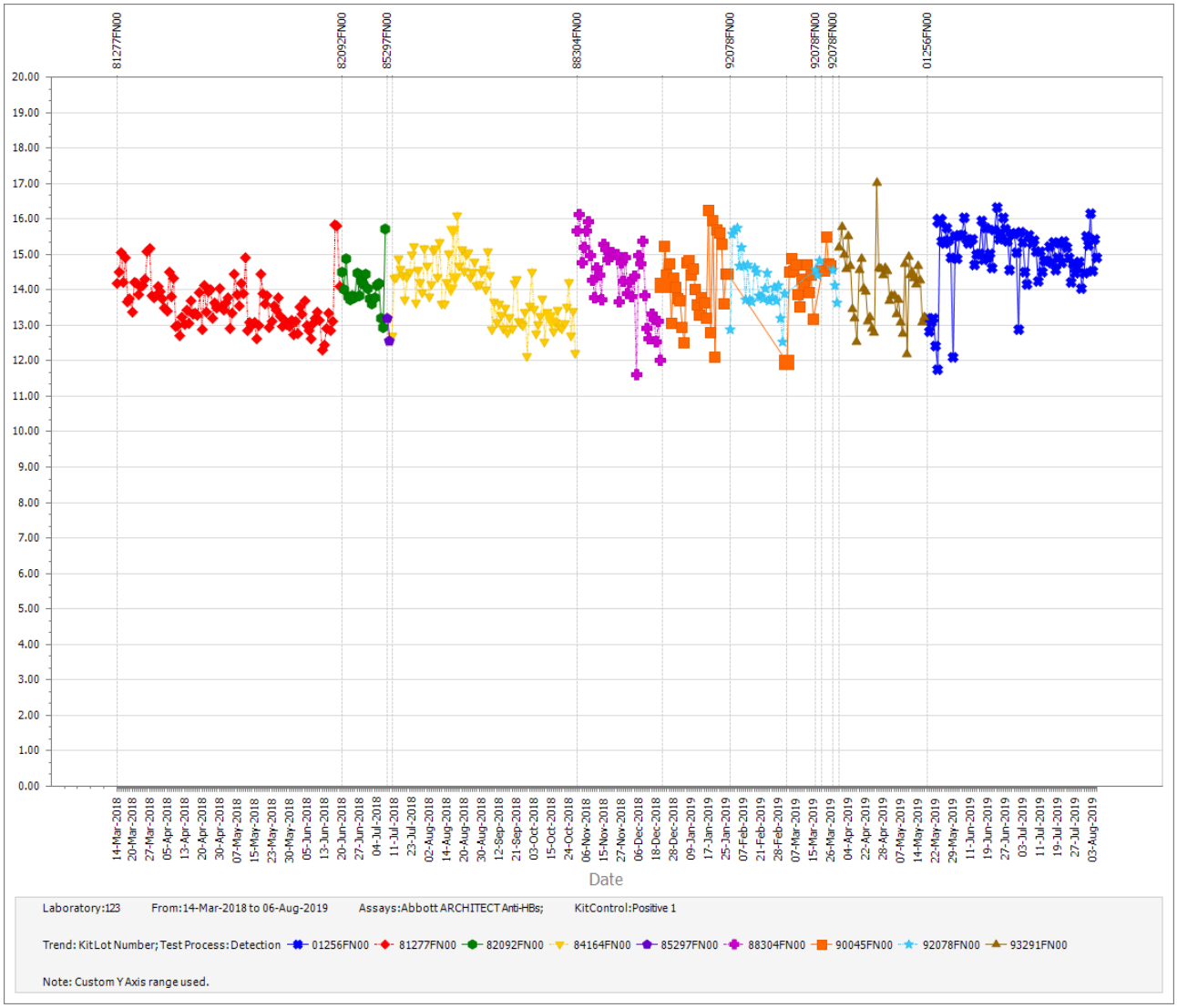
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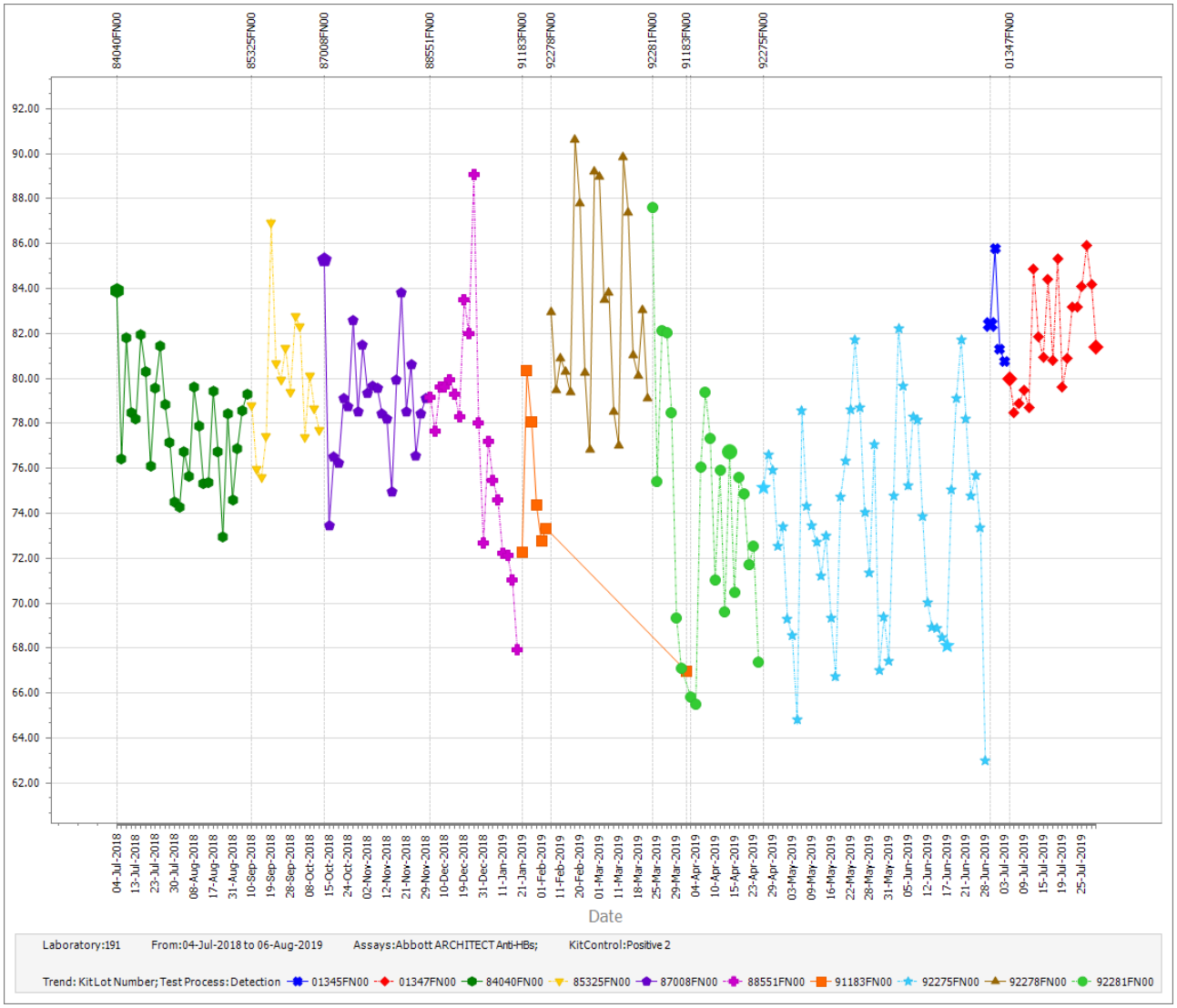
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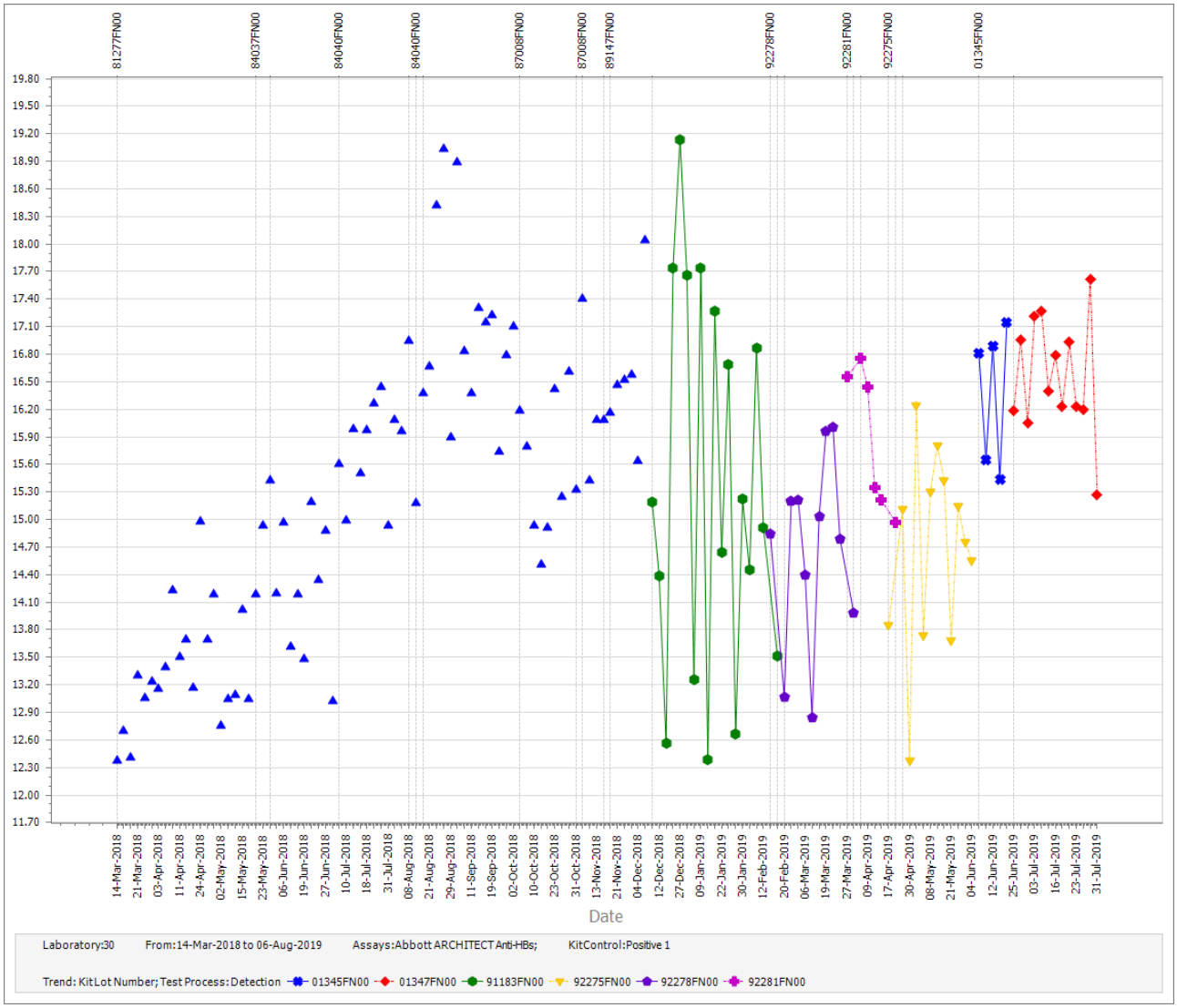
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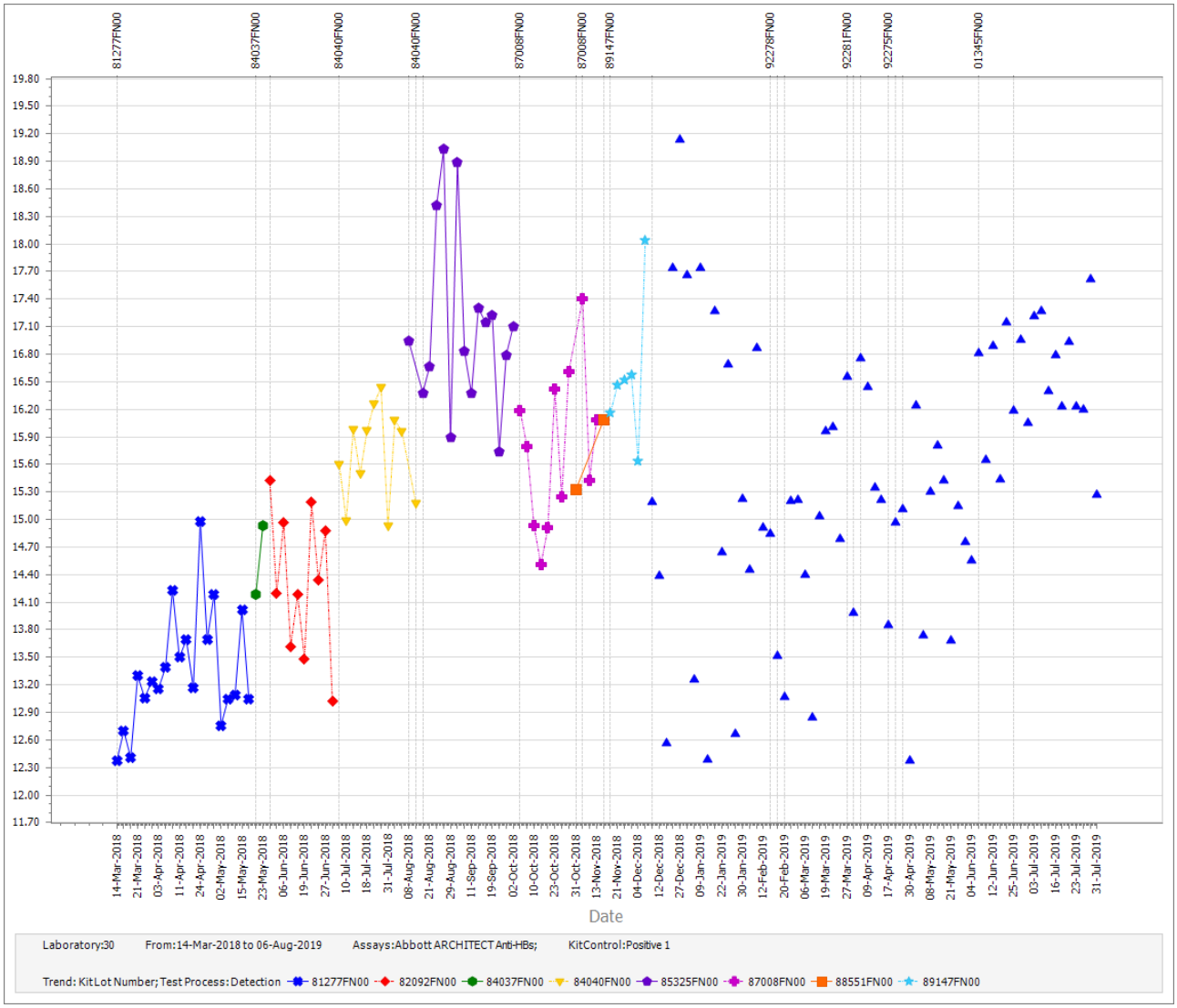
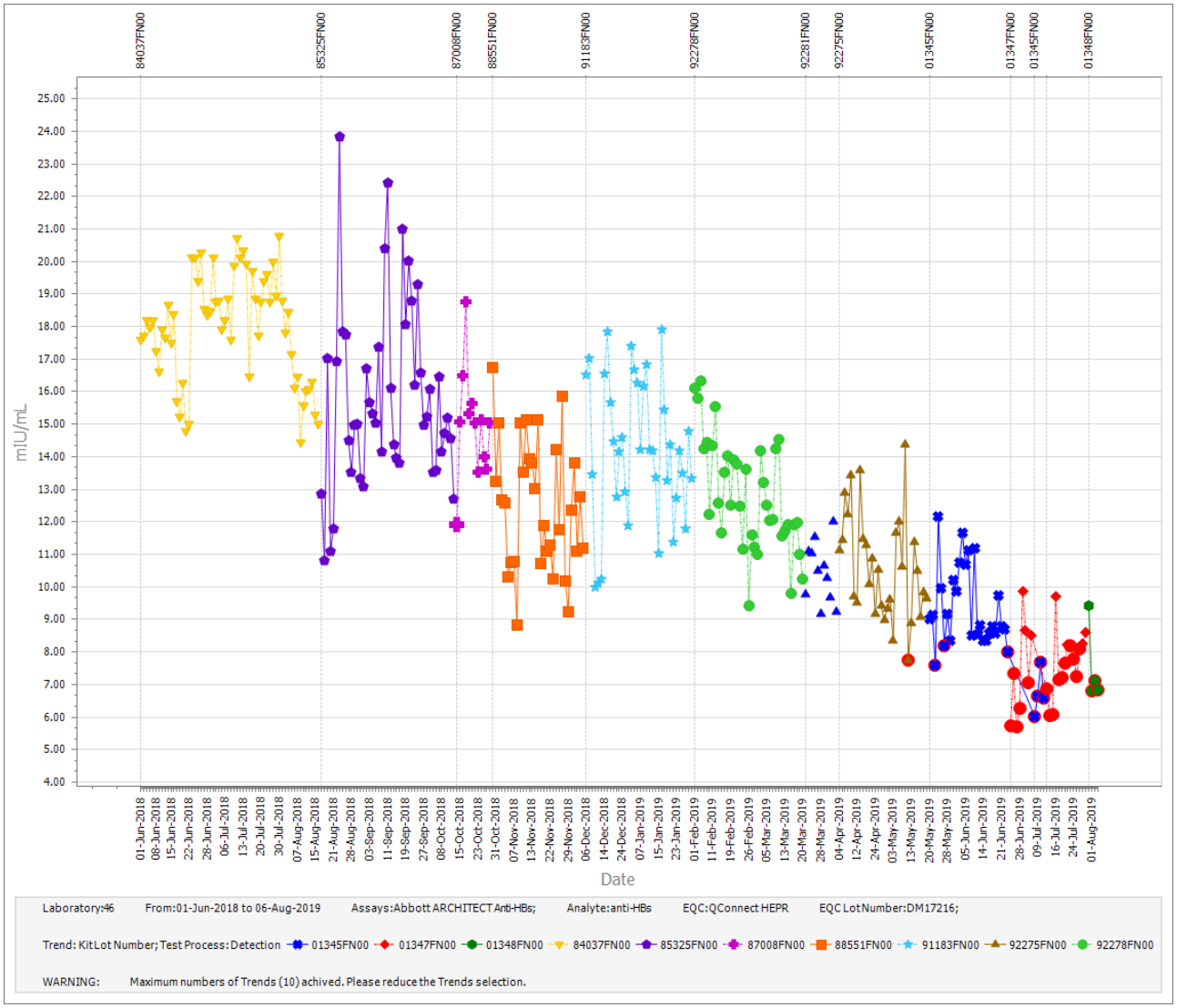
13-Nov-2018
21-Nov-2018
04-Dec-2018
12-Dec-2018
27-Dec-2018
09-Jan-2019
22-Jan-2019
30-Jan-2019
12-Feb-2019
20-Feb-2019
06-Mar-2019
19-Mar-2019
27-Mar-2019
09-Apr-2019
17-Apr-2019
30-Apr-2019
08-May-2019
21-May-2019
04-Jun-2019
12-Jun-2019
25-Jun-2019
03-Jul-2019
16-Jul-2019
23-Jul-2019
31-Jul-2019
Date
Laboratory:30
From:14-Mar-2018 to 06-Aug-2019
Assays:Abbott ARCHITECT Anti-HBs;
KitControl:Positive 1
Trend: Kit Lot Number; Test Process: Detection
01345FN00
01347FN00
91183FN00
92275FN00
92278FN00
92281FN00


81277FN00
84037FN00
84040FN00
84040FN00
87008FN00
87008FN00
89147FN00
92278FN00
92281FN00
92275FN00
01345FN00
Date
Laboratory:30
From:14-Mar-2018 to 06-Aug-2019
Assays:Abbott ARCHITECT Anti-HBs;
KitControl:Positive 1
Trend: Kit Lot Number; Test Process: Detection
81277FN00
82092FN00
84037FN00
84040FN00
85325FN00
87008FN00
88551FN00
89147FN00


84037FN00
85325FN00
87008FN00
88551FN00
91183FN00
92278FN00
92281FN00
92275FN00
01345FN00
01347FN00
01345FN00
01348FN00
mIU/mL
Date
Laboratory:46 From:01-Jun-2018 to 06-Aug-2019 Assays:Abbott ARCHITECT Anti-HBs; Analyte:anti-HBs EQC:QConnect HEPR EQC Lot Number:DM17216;
Trend: Kit Lot Number; Test Process: Detection 01345FN00 01347FN00 01348FN00 84037FN00 85325FN00 87008FN00 88551FN00 91183FN00 92275FN00 92278FN00
WARNING: Maximum numbers of Trends (10) achived. Please reduce the Trends selection.