



Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Date: 21 December 2023

To Whom It May Concern

RE: Revised Field Safety Notice (FSN) for ID Now Instrument FSCA (Identifier 2023 09)

This notice is to inform you of a correction made to the original Field Safety Notice (FSN), FSCA Identifier 2023 09 that was provided on 19 October 2023.

We identified an inadvertent omission of an additional part number (NAT-000S) for the refurbished ID NOW Instrument and the Alere I from the original FSN. While this part number was omitted from the original FSN, it was however included as part of the impacted part numbers within the original FSCA Report filed.

This oversight was only on the original FSN and has been resolved in the attached revised FSN.

In addition, please note that any subsequent data that may have been provided after the initial FSCA communication, does contain the correct data i.e., it included both part numbers (NAT-000 and NAT-000S) of the ID NOW instrument and were therefore not impacted by this error.

The distribution of the software upgrade is in progress. We anticipate distribution to be completed 31DEC2023 and we will provide an update to the implementation plan through an FSCA follow-up report.

Please do not hesitate to contact us at ARDX.AR@abbott.com if you have any queries or require further information.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Jeanette Johnson', written over a horizontal line.

Jeanette Johnson
Director, QA Post Market Surveillance
Abbott Diagnostics Scarborough, Inc