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25 June 2024

Kate Bryant  
Coroners Registrar  
Coroners Court of Victoria  
65 Kavanagh Street  
Southbank 3006

**RESPONSE FROM ABBOTT'S POINT OF CARE DIAGNOSTICS  
(COURT REFERENCE NUMBER: COR 2022 000978)**

Dear Registrar,

We refer to the letter from the Court dated 15 April 2024 in relation to His Honour Coroner McGregor's Finding without inquest into the death of Adelaide Wilson.

We are deeply saddened by the death of Ms. Adelaide Wilson, and we express our sincere condolences to the family and friends of Ms. Wilson.

**His Honour Coroner McGregor's Recommendation**

We note that Coroner McGregor made the following recommendation in relation to Abbott Point of Care Diagnostics:

*"I recommend that Abbott point of care diagnostics consider a software update for i-STAT-1 machines that includes reference ranges, interpretation of result and other cognitive aids."*

Pursuant to Section 72(3) of the Coroners Act 2008 (Vic), we set out our response to Coroner McGregor's recommendation below.

**Abbott Point of Care Diagnostic's Response**

Based on our investigation, we can confirm that the reference ranges, interpretation of results and cognitive aids, as referred to in the Coroner's recommendation, are currently part of the i-STAT 1 analyzer's (machine's) system features and functionality.

As set out in the i-STAT 1 System Manual, the i-STAT 1 analyzer can be customized by each user for the following:



**Abbott**

- Reference Ranges - Reference ranges can be defined for each test. Ranges will be displayed on the Customization screen of the handheld under the Administration Menu.
- Action Ranges - High and low action ranges can be defined for each test (↑ up arrow indicates the result is above the high action range, ↓ down arrow indicates the result is below the low action range).
- Customer Reportable Ranges - High and low custom Reportable Ranges can be defined for each analyte (except ACT).
- Print Reference Ranges - Reference Ranges can be printed with results. Ranges will print only if the record to be printed is stored with the active Preference set in the handheld. The active Preference set in the handheld is listed as "Custom" on the Analyzer Status page and the Preference set stored with the record is displayed on the Chart Page when the record is recalled and is printed with the results.

The System Manual for the i-STAT 1 analyzer also describes the interpretation of results, including: Reportable range, Reference Range, Action Ranges and Flags.

Customization instructions are included in the System Manual for the i-STAT 1 analyzer and the Data Management User Guide, including screenshots of the Customization Workspace and the analyzer screen to aid the user in selecting the correct preferences.

Therefore, the i-STAT 1 analyzer has the functionality to display reference ranges and flag abnormal results, and instructions are detailed in the System Manual for the i-STAT 1 analyzer and the Data Management User Guide.

Based on the above, the Coroner's recommendation is already in place and a software update for the i-STAT 1 analyzer, for the purposes set out in the Coroner's recommendation, is not required.

We thank the Court and His Honour Coroner McGregor for the time and attention to this matter. Should you or any of the healthcare providers have any questions regarding this response, please contact Abbott [REDACTED]

Regards,

A handwritten signature in blue ink, appearing to read 'Linda Maczuszenko'.

Linda Maczuszenko  
Director, Product Quality Abbott Point of Care  
Incident 949196