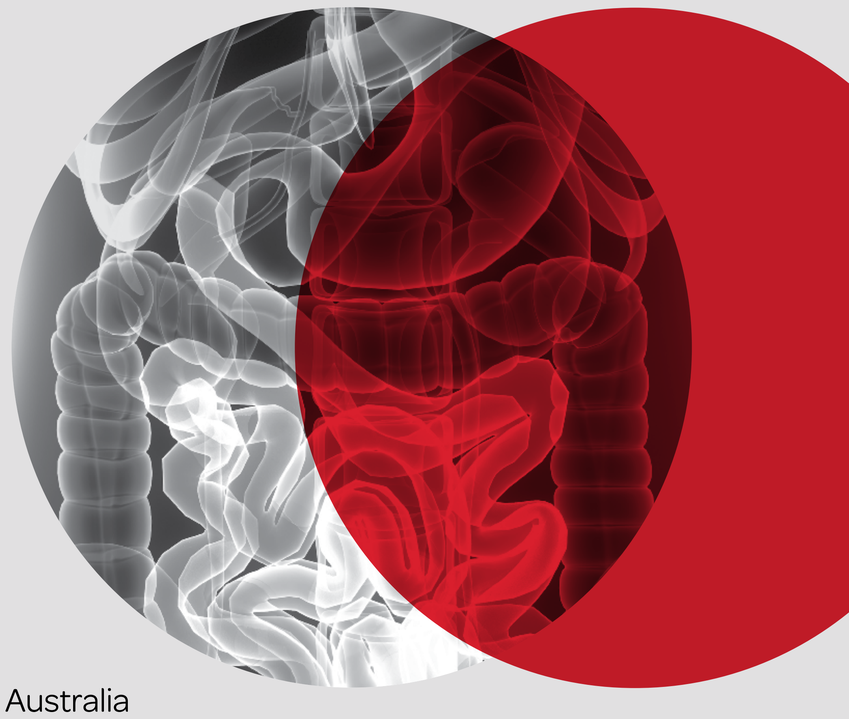
External quality assurance program for small intestine disaccharidases



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Introduction

The RCPAQAP sought to develop an External Quality Assurance (EQA) Program for disaccharidase assays (primarily lactase, sucrase and maltase). These assays are performed to evaluate the enzyme activity of the small intestine to assist in the diagnosis of patients with enzyme deficiencies which can contribute to chronic bowel conditions.

In practice, the sample tested is a piece of bowel lumen biopsied during endoscopy or colonoscopy. The sample needs to be transported to the laboratory cold and in parafilm to prevent the tissue dehydrating. To date, some laboratories had tried pig gut as a possible sample for an EQA. Obtaining a homogenous, stable sample proved challenging. We attempted to replicate a tissue homogenate using commercially available enzymes and protein and test it's suitability as an EQA material.

Method

Enzyme supplements containing lactase, sucrase and maltase, sourced from a commercial supplier (Sigma-Aldrich) were used to spike a human albumin base solution. Low and high concentration pools were then blended to obtain six linearly related samples. The samples were aliquoted and freeze-dried to maintain stability. Pre-testing of samples during the development phase was kindly provided at RNSH using a Modified Dalquist methodology. The EQA program was subsequently launched in March 2021 and the returned results from nine enrolled labs were assessed.

Results and Discussion

The initial data showed acceptable linearity over six levels (Figure 1), further refinement was made to cover a range of values at different protein levels.

The returned medians for the low, mid and high levels from the first three 2021 surveys are shown in Table 1. These cover the reference intervals in use by most laboratories. While there is considerable variation in reference intervals across the participating laboratories, we noted medians of >20, >33 and >88 U/g protein for Lactase, Sucrase and Maltase respectively.

Initial stability data indicates the lyophilised material should be stable over at least 12 months, this is supported by the repeat data for level 5 between April and August 2021 (Table 2).

Conclusion

The RCPAQAP Disaccharidase program was launched in February 2021 and offers the first of it's type. Further review of the submitted results will help inform laboratories performing these assays on the degree of harmonisation of results.

Figure 1. Linearity and enzyme levels for samples A-F in a common protein base in the development samples

Table 1. Medians from the returned results for Levels 1, 4 and 6

Level	Lactase Median (U/g Protein) (n=9)	Sucrase Median (U/g Protein)(n=9)	Maltase Median (U/g Protein)(n=9)
1 (Low)	1.0	14.0	10.0
4 (Mid)	6.0	103.0	75.0
6 (High)	39.5	160.0	268.0

Table 2. Table 2 Evidence of 4 month stability on Level 5 samples

Measurand	April 2021 Median (U/g Protein) (n=9)	August 2021 Median (U/g Protein) (n=9)	% Change
Lactase U/g Protein	6.0	5.5	-8.3
Sucrase U/g Protein	103.0	96.0	- 6.8
Maltase U/g Protein	75.0	71.0	-5.3
Protein (mg/L)	1050	1100	+4.7

Acknowledgement

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