Review of a Calprotectin EQA Program

Peter Graham, Jonathan Bush, Abrar Taif

The Royal College of Pathologists of Australasia Quality Assurance Programs, St Leonards, NSW, 2065, Australia

Introduction

Elevated Calprotectin in a faecal sample is a diagnostic indicator of inflammatory bowel disease (IBD). Low levels of Faecal Pancreatic Elastase are consistent with pancreatic insufficiency.

The Royal College of Pathologists Australasia Quality Assurance Programs (RCPAQAP) introduced a Faecal Calprotectin / Pancreatic Elastase External Quality Assurance (EQA) program in June 2023. The program consists of six lyophilised faecal samples (3 x 2 sample surveys) sourced from donated human faeces. We sought to review the performance of participating laboratories in the initial 2023 surveys.

Methods

Lyophilised faecal samples, prepared in-house by RCPAQAP, were dispatched to enrolled participants in May 2023, a total of 15 sites returned quantitative results and/or qualitative interpretations (Positive, Equivocal, Normal) for Calprotectin, and 9 for Elastase. The qualitative results were assessed as either Concordant or Discordant, based on a consensus of >80%. Quantitative results were assessed against APS's initially set as +/- 15-20% of the "All Result" medians.

Results

Diasorin Liaison (n=7) and Thermo Fisher Phadia (n=4) are the most popular methods. Other enrolled methods (Berthold LB 925, Binding Site Optilite, CerTest, Ortho-Clinical and Werfen BIO-FLASH) had insufficient numbers to compare within their respective peers (all n=1).

Samples 23-01, 03 and 04 returned Positive qualitative consensus results for calprotectin consistent with quantitative medians > 100ug/g , however CV's ranged from 61.4 to 74.8% (Table 1). Diasorin and Phadia method medians were comparable for 3 of the 4 samples (Figure 1). Sample 23-02 achieved a Normal (97%) consensus with a with a quantitative median of 9 ug/g (CV 71.4%) (Table 1). While all 4 samples had quantitative medians for Elastase > 200ug/g, the majority of participants Elastase returned "Positive" qualitative interpretations when the intended result was "Normal". Elastase CV's ranged from 20.6 to 38.8 (Table 2).

Discussion and Conclusion

The initial results for this new program were consistent with the expected results from the donated samples, however, the scatter of results, as indicated by the CV's, may be due to pre-analytical (sampling) differences. While the samples are designed to match the consistency of the original faeces after reconstitution (to enable testing as for a patient) some sites reported having to use their liquid protocol vs direct "weight". This may also have contributed to the between method differences. To avoid confusion, a change to the qualitative reporting options (from Pos, Neg, Equivocal to Normal, Abnormal, Equivocal) has been implemented for 2024 reporting.

Table 1 Summary of Calprotectin results for the initial 4 QAP samples for Diasorin Liaison and Thermo Fisher Phadia methods

Sample No	All results n=15			Diasorin n=7			Phadia n=4			Qual
	Median	Mean	CV%	Median	Mean	CV%	Median	Mean	CV%	
23-01	110	120	61.4	80	83	37.0	94	99	41.5	Pos
23-02	9	12	71.4	6	7	35.0	10	9	21.6	Neg
23-03	770	1108	69	800	858	22.4	703	669	12.4	Pos
23-04	640	788	74.8	452	479	30.5	1140	1425	48.9	Neg

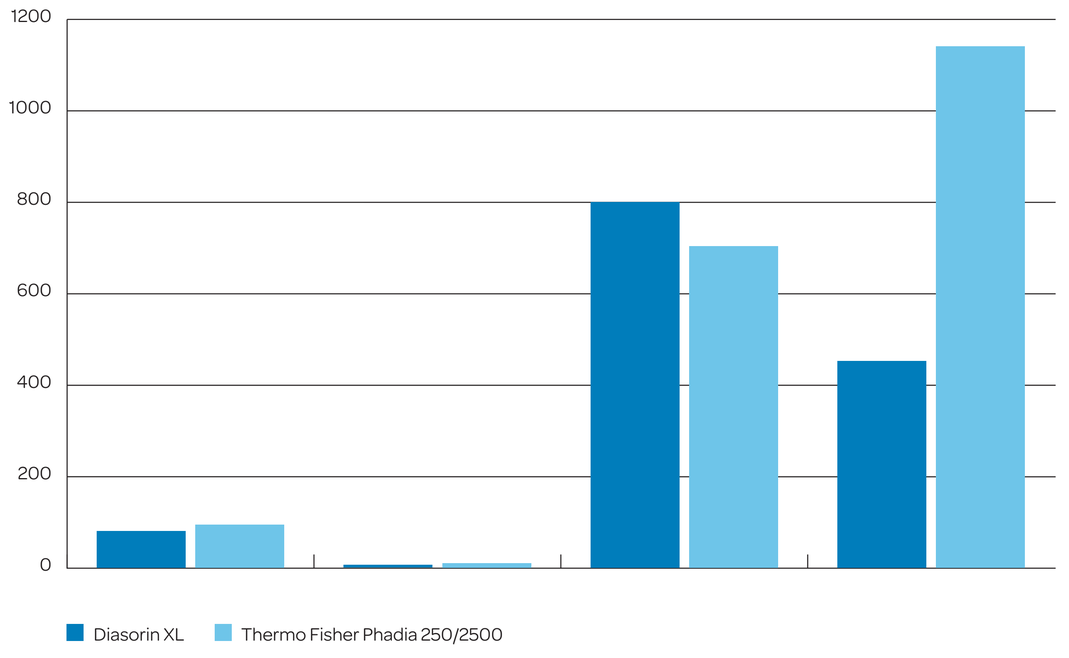

Figure 1 Comparison of medians for Diasorin and Thermo Fisher Phadia methods for Samples 23-01, 02, 03 and 04

Table 2 Summary of Elastase results for the initial 4 QAP samples

Sample No	All results n=9			Diasorin n=7			Qual
	Median	Mean	CV%	Median	Mean	CV%	
23-01	322	372	30.2	359	408	30.2	Pos
23-02	317	309	20.6	317	309	20.6	Pos
23-03	201	205	23.6	209	215	22.6	Pos
23-04	800	647	38.8	800	754	11.3	Pos