LACTOFERRIN ASSAY

Gastro Health Marker

The Diazyme Lactoferrin Assay is immunoturbidimetric assay used for the quantitative measurement of Lactoferrin in human fecal samples.

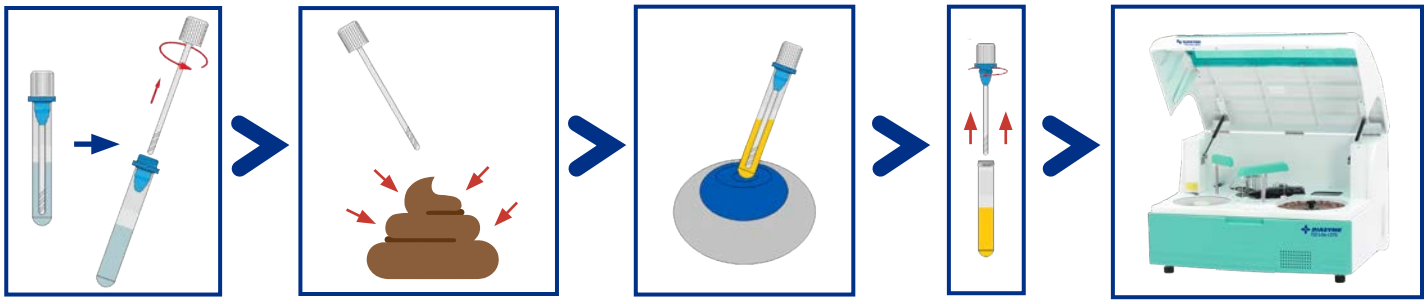
Studies have shown that fecal lactoferrin can serve as reliable biomarker, primarily focusing on gastrointestinal health and inflammatory conditions.[1] By quantifying lactoferrin levels in bodily fluids, clinicians can assess the presence and severity of inflammation, particularly in the gastrointestinal tract. Elevated lactoferrin concentrations are indicative of mucosal damage or inflammation, serving as a valuable marker for Inflammatory Bowel Disease (IBD) such as Ulcerative Colitis (UC), and Crohn's Disease (CD).[2]

DIAZYME LACTOFERRIN ASSAY ADVANTAGES

- Particle-enhanced immunoturbidimetric method
- Liquid stable reagent kit, calibrator and control sets offered separately
- Fast test results (10 minutes) for a rapid turnaround time
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

USA: For Research Use Only. Not for Use in Diagnostic Procedures.



DIAZYME
Innovations in Clinical Diagnostics

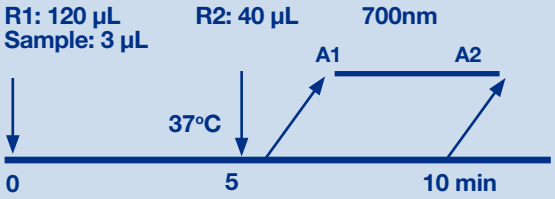
LACTOFERRIN ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Particle Enhanced Immunoturbidimetric
Sample Type & Volume	Stool extracts Sample Volume 3 µL
Method Comparison	N: 39 Slope = 0.9 y-intercept = -0.6 R^2 = 0.82
Linearity	1.5 to 100 µg/g (AMR)
LOB LOD LOQ	0.5 µg/g 1.006 µg/g 1.5 µg/g
Calibration Levels	6-Point Calibration
Prozone/Hook Tolerance	up to 10,000 µg/g
Reagent On-Board Stability	30 days on-board stability (when stored at 2-8°C)

LACTOFERRIN ASSAY



For a list of validated parameters please contact Diazyme technical support at 858-455-4768 or email support@diazyme.com

REFERENCES

1. *Yamamoto, Takayuki. "The Clinical Value of Faecal Calprotectin and Lactoferrin Measurement in Postoperative Crohn's Disease." United European Gastroenterology Journal, vol. 3, no. 1, 1 Feb. 2015, pp. 5–10, www.ncbi.nlm.nih.gov/pmc/articles/PMC4315679/#bi-br13-2050640614558106,*
2. *Reenaers C, Bossuyt P, Hindryckx P, Vanpoucke H, Cremer A, Baert F. Expert opinion for use of faecal calprotectin in diagnosis and monitoring of inflammatory bowel disease in daily clinical practice. United European Gastroenterology Journal. 2018;6(8):1117-1125. doi:10.1177/2050640618784046*

ASSAY PRECISION

The precision of the Diazyme Lactoferrin Assay was evaluated on an AU680 analyzer according to CLSI EP5-A2 guideline. Five samples were tested with 2 replicates with two run per day for 20 days for a total of 80 replicates per sample. Results are summarized below.

Sample	Mean (µg/g)	n	Within Run		Between Run		Between Day		Total	
			SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	2.8	80	0.2	8.0	0.2	8.1	0.3	8.9	0.3	12
2	9.0	80	0.4	4.0	0.4	4.2	0.7	7.5	0.8	8.6
3	20.9	80	0.4	1.8	0.8	3.6	0.8	3.7	1.0	4.7
4	45.2	80	1.0	2.2	1.6	3.6	1.6	3.6	2.1	4.7
5	75.9	80	2.3	3.0	2.4	3.2	4.7	6.2	5.2	6.9

ACCURACY & RECOVERY

Five extracted stool samples containing various concentrations of Lactoferrin across the analytical measuring range of the assay were spiked with native Lactoferrin. The stool sample extracts were mixed with the spiking material to add an expected amount of 23 µg/g . Recovery was calculated compared to the baseline result. The spiked sample recoveries were within 10% of the expected values. The results of the recovery study is summarized below.

Specimen Extract	Mean Baseline Result (µg/g)	Spiked Value (µg/g)	Expected Post-Spike Result (µg/g)	Observed Post-Spike Result (µg/g)	Recovery (%)
1	16.7	23	39.7	39.5	99.5
2	26.1	23	49.1	48.9	99.59
3	22.1	23	45.1	44.9	99.56
4	24.1	23	47.1	46.9	99.58
5	37.1	23	60.1	59.9	99.67

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