

**CERTIFICATE OF ANALYSIS**  
**BECKMAN FERRITIN REAGENTS**

	Ferritin Buffer	Ferritin Particle
Beckman Part Number	447168	447167
Vendor Part Number	447168	447167
Vendor Lot Number	72259558	72259559
Date of Bulk Manufacture	18 FEB 16	12 FEB 16
Date of Final Filtration	18 FEB 16	N/A
Expiration Date	18 FEB 18	12 FEB 18
Quantity	15,700	11,800
Storage Condition:	2-8 °C	2-8 °C
Beckman SCD Revision Letter	AH	AH
Vendor's Process Revision Letter	M	O

	Materials	Lot Number	Expiration Date
Instrument	Immage, S/N 1003	N/A	N/A
Reagents	On-Test Reagent	Buffer Particle	72259558 72259559
	Master Reagent	Buffer Particle	72158260 72158284
Calibrators	Master Lot	60569650-57	31 MAR 19
	Ferr Cal (200)	M408001	30 APR 17
Secondary Standard (diluted)	Approx 75 ng/mL	021916	19 FEB 18
	Approx 200 ng/mL	021916	19 FEB 18
	Approx 350 ng/mL	021916	19 FEB 18
Prozone Calibrator	450 ng/mL	022416	24 FEB 18
Prozone Samples	30,000 ng/mL	10159507	18 MAY 16
	10,000 ng/mL	10159504	18 MAY 16
	1,000 ng/mL	10159502	18 MAY 16
	600 ng/mL	10159501	18 MAY 16
Pooled Patient Samples	Pool #1: Approx 50 ng/mL	021916	19 FEB 18
	Pool #2: Approx 200 ng/mL	021916	19 FEB 18
	Pool #3: Approx 350 ng/mL	021916	19 FEB 18
Controls	BioRad Liquicheck Plus	40870	30 NOV 16
	BioRad Lypocheck Anemia	43230	31 AUG 16

## Beckman Ferritin Reagents

Lots: 72259558 / 72259559

Product	Parameter	Specification	Result	Pass/Fail
Ferritin Buffer	Appearance	Clear, light yellow liquid, essentially free of visible foreign matter	Clear, light yellow liquid, essentially free of visible foreign matter	PASS
	pH	8.2 ± 0.2	8.2	PASS
	Microbial Count	< 100 CFU/mL	0.8 CFU/mL	PASS
Ferritin Particle	Appearance	Milky white opaque suspension, essentially free of visible foreign matter	Milky white opaque suspension, essentially free of visible foreign matter	PASS
	Microbial Count	< 1000 CFU/mL	0 CFU/mL	PASS

Test	Specification	Result		Pass/Fail	
		On-Test	Master		
Calibration % Error	≤ 5% or ≤ 2.5 ng/mL, whichever is greater (at 25 to 550 ng/mL)	-0.3 ng/mL	0.1 ng/mL	PASS	
Calibrators Rate Span	Level J-A (550-0):	12.6 - 15.2	13.9	14.1	PASS
	Level D-A (25-0):	0.35 - 0.61	0.42	0.44	PASS
	Level G-F (200-100):	2.0 - 3.5	2.3	2.3	PASS
	Level I-H ( 500-350):	3.1 - 5.1	4.5	4.8	PASS
Master Calibrator from Uncalibrated Curve Fit	Level A (0 ng/mL):	< 5 ng/mL	1	N/A	PASS
	Level D (25 ng/mL):	20-30 ng/mL	25	N/A	PASS
	Level E (75 ng/mL):	68-83 ng/mL	75	N/A	PASS
	Level F (100 ng/mL):	90-110 ng/mL	102	N/A	PASS
	Level G (200 ng/mL):	190-210 ng/mL	199	N/A	PASS
	Level H (350 ng/mL):	332-368 ng/mL	337	N/A	PASS
	Level I (500 ng/mL):	463-538 ng/mL	509	N/A	PASS
Level J (550 ng/mL):	510-590 ng/mL	545	N/A	PASS	
Master Calibrator X-Dilution Run	Level A (0 ng/mL):	< 3 ng/mL	0	N/A	PASS
Ferr Cal (200) Recovery	190 – 210 ng/mL	198	N/A	PASS	
Prozone Samples	Prozone Cal Rate (450 ng/mL)	468	N/A	FIO	
	30,000 ng/mL Rate: > Prozone Cal Rate	660	N/A	PASS	
	10,000 ng/mL Rate: > Prozone Cal Rate	798	N/A	PASS	
	1,000 ng/mL Rate: > Prozone Cal Rate	762	N/A	PASS	
	600 ng/mL Rate: > Prozone Cal Rate	610	N/A	PASS	
Master Calibrator Linear Regression (observed vs. expected)	Slope:	0.95 – 1.05	1.00	N/A	PASS
	Intercept:	0 ± 2.5 ng/mL	0.0	N/A	PASS
	R:	≥ 0.98	1.00	N/A	PASS

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Test	Specification	Result		Pass/Fail
		On-Test	Master	
Control Recovery	Control 1 - Within Spec Range: 10.5 – 25.5 ng/mL Within ± 10.0% or ± 5.0 ng/mL of Master Reagent	23.1 -4.5%	24.2 N/A	PASS PASS
	Control 2 - Within Spec Range: 69.5 – 104.2 ng/mL Within ± 10.0% of Master Reagent	89.0 2.3%	87.0 N/A	PASS PASS
	Control 3 - Within Spec Range: 153 – 229 ng/mL Within ± 10.0% of Master Reagent	190 1.0%	188 N/A	PASS PASS
	Anemia Control - Within Spec Range: 5.95 – 8.53 ng/mL Within ± 12.5% or ± 6.25 ng/mL of Master Reagent	7.37 -8.6%	8.10 N/A	PASS PASS
Secondary Standards	75 ng/mL: Within ± 5.0% of Master Reagent	74.0 2.4%	72.3 N/A	N/A PASS
	200 ng/mL: Within ± 5.0% of Master Reagent	196.5 2.3%	192.1 N/A	N/A PASS
	350 ng/mL: Within ± 5.0% of Master Reagent	338.7 3.9%	325.9 N/A	N/A PASS
Pooled Patient Samples	Pool #1: Within ± 10.0% of Master Reagent	40.8 -1.2%	41.3 N/A	N/A PASS
	Pool #2: Within ± 10.0% of Master Reagent	175.5 5.7%	166.1 N/A	N/A PASS
	Pool #3: Within ± 10.0% of Master Reagent	304.4 -0.2%	304.9 N/A	N/A PASS
Patient Sample Correlation	N: ≥ 30	37	N/A	PASS
	Slope: 0.92 – 1.08	1.01	N/A	PASS
	Intercept: ± 8.0 ng/mL	-6.9	N/A	PASS
	R: ≥ 0.95	1.00	N/A	PASS



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**Beckman Ferritin Reagents**  
**Lots: 72259558 / 72259559**

APS data filenames:

Master

On-Test

Calibration curve file:

- FER-F722595 Analysis 1
- FER-F722595 Analysis 1
- FER-F722595 Analysis 1

- FER-F722595 Analysis 1
- FER-F722595 Analysis 1
- FER-F722595 Analysis 1

APS unknown data file:

- FER-F722595 Analysis 1
- FER-F722595 Analysis 1
- FER-F722595 Analysis 1

- FER-F722595 Analysis 1
- FER-F722595 Analysis 1
- FER-F722595 Analysis 1

Completed by: Amia

Date: 3/14/2016

Quality Approval: Dulles

Date: 3/14/16