



CERTIFICATION OF ANALYSIS

Product meets physical inspection requirements per Abbott PSCP.09P6022 and Abbott MS.Master342.

CUSTOMER: ABBOTT

CUSTOMER PO# 4800227108

ENTIRE LOT QUANTITY: 51

QUANTITY THIS SHIPMENT: 51

PRODUCT: Alinity i Galectin-3 Reagent Pack 2 X 100		
FDI ITEM #: C708-100	REAGENT INSERT #: 708-325 R01	ADD LIST NUMBER: 09P6022
FDI LOT # C7K02421	ADD LOT NUMBER: 27098FP00	
EXPIRATION DATE: 2022-02-25	ADD MATERIAL NUMBER: 09P6022	

REAGENT PACK INFORMATION

Reagent	FDI Item #	FDI Lot #	ADD Lot #	Expiration Date
Conjugate	708-025	C7J00621	27098FP00	2022-02-25
Microparticle	708-010	C7U00621	27098FP00	2022-02-25
Spacer	708-990	C7K02421	27098FP00	2022-02-25

RELEASE FOR SALE TESTING RESULTS

Parameter	Specification	Assay Results Mean of ≥ 30 Replicates	Pass / Fail
Reference Low Control	8.30 – 9.90 ng/mL	9.01	Pass
Reference Medium Control	18.10 – 22.90 ng/mL	19.47	Pass
Reference High Control	64.10 – 84.10 ng/mL	74.41	Pass

BARCODE VERIFICATION RESULTS PERFORMED ON ALINITY INSTRUMENT

Instrument Field	Displayed Output	Pass / Fail
Lot Number	Matches Cartridge Labeling	Pass
Expiration	Matches Cartridge Labeling	Pass
Onboard Stability (hrs)	720	Pass
Assay Name	Galectin-3	Pass
Assay Number	576	Pass
SN	Matches Serial Number on Cartridge Labeling	Pass

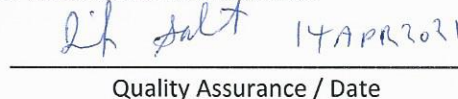
The above product has been manufactured in accordance with Fujirebio Diagnostics, Inc. operating procedures.

Each shipment of a lot conforms to the controlled production documents and the product is identical to previous shipments of this lot.

This material meets all Quality Release Criteria and is found to be acceptable for shipment.

This product contains animal source material. The bovine material used in the manufacture of this product is derived from serum/plasma of animals located in the USA and New Zealand.


Quality Assurance / Date


Quality Assurance / Date



201 Great Valley Parkway
Malvern, PA 19355
1-800-342-9225

FDI-QA-CofA-0360
Revision 001
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