

Document No: 09P4140Effective Date: 19 Feb 2020Edition No: 01DVendor Spec Date: 19 Feb 2020Name: Alinity i Sirolimus Whole Blood Precipitation Reagent

Alinity i Sirolimus Whole Blood Precipitation Reagent

Supplier Name: Fujirebio (Seguin, TX)	Supplier Product Number: 4008254	Abbott Material/List Number: 09P4140	Legal Manufacturer: Abbott
Storage Conditions: 15 to 30 degrees C			
Shelf Life: 18 months from the date of manufacture of the bulk material			
Instructions: Refer to the current edition of MS.MASTER342, Appendix B Refer to the current edition of MS.MASTER333 Refer to the current edition of MS.MASTER351 Refer to the current edition of MS.MASTER353			

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Supplier Specifications

**Supplier
Special
Instructions**

N/A

**General
Product
Requirements**

Batch/Lot Number: Refer to Quality Agreement DFP06.OEM060	File Sample Retention Requirements: Refer to Quality Agreement DFP06.OEM060	Minimum Remaining Shelf Life: 14 months (or less with written Abbott Planning/ Purchasing approval) when delivered to Abbott.
Shipping: Ambient.		
Packaging: Kit Drawing AK4325R1 MS.MASTER342, MS.MASTER333, MS.MASTER353		
Kit Contents: 1 bottle Precipitation Reagent 1 Precipitation Reagent label 1 Alinity i Sirolimus Whole Blood Precipitation Carton Label 1 Alinity i Sirolimus Whole Blood Precipitation Package Insert 1 USA Information Only Kit Label		

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Product
Requirements**
(continued)

Using components listed below, assemble kit per drawing number listed above.

Printed Kit Contents			
Label Name	Commodity Number	Quantity per Kit	TXT
Precipitation Reagent Label	093390.00 Rev 000	1	N/A
Alinity i Sirolimus Whole Blood Precipitation Carton/Kit Label	093389.00 Rev 000	1	09P4101
Alinity i Sirolimus Whole Blood Precipitation Package Insert (ALMS Control Number)	093438.00 Rev 000 R04	1	N/A
USA Information Only Kit Label	093437.00 Rev 000 R01	1	N/A
Product Assigned GTIN: 00380740154233			

Commodities		
Component Description	Component Number	Quantity per Kit
Bottle, 35ML, HDPE, Natural	99-0917	1
Cap 24 mm, White	99-0973	1
Fiberboard Insert	77-4002	1
Carton, Precipitation Reagent	G94354R01	1

*No commodity number on label

Packing and marking:

Packing instructions:

- Pack 09P4140 kit per package assembly drawing listed in the description section.
- Precip reagent will ship from TPM to Abbott ambient.

For additional requirements, refer to the current edition of MS.MASTER342.

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Analysis**

The certificate must include the following information:

Note: Per Fujirebio Diagnostic's procedures, when present, a letter positioned to the right of the kit lot number is a run identification indicator and is not part of the lot number. The run identification indicator represents an additional packaging operation. If a run indicator is necessary, additional assay results will appear on the Certificate.

- Acceptance requirements of visual/functional testing results including acceptance ranges and final release values.

Acceptance Ranges	
Parameter	Specification
Panel 1	Lot Specific – Assigned on COA
Panel 2	Lot Specific – Assigned on COA
Conductivity	86.78-102.66 µmhos

For additional requirements, refer to the current edition of MS.MASTER342.

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Supplier Specifications, Continued

Performance Requirements

Note: AQL = Acceptable Quality Level

Attribute	Description	AQL
Functional	Panel 1	Pass/Fail
	Panel 2	Pass/Fail
	Conductivity	Pass/Fail
Miscellaneous	Kit expiration date will not exceed the expiration date of the shortest dated component.	Pass/Fail
	<ul style="list-style-type: none"> • All corrugated boxes in the shipment must be packed as described. • All corrugated boxes in the shipment must be marked as described. • Certificate is required and as described. 	Pass/Fail

Value Assignment Requirements

N/A

End of Supplier Specifications

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Abbott Specifications

Sampling and Testing Requirements

Samplin g Stage	Sample Amount	Test Name	Acceptance Criteria	Results
1-F	No Sample Required	Certificate	Pass supplier specifications per this PSCP	Pass/Fail
1-F	No Sample Required	Physical Inspection	Pass supplier specifications per this PSCP, MS.MASTER342 and form DIV08182	Pass/Fail/Cancel
1-F	3 Kits	File Samples	N/A	N/A
1-F	2 Kits	Technical Support Samples	N/A	N/A

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