ImmunoReagents Inc.	Checklist (CL)		Page 1 of 1
	Form:	CL-006	
	Title:	Expiration Date Extension Checklist	
Document Effective Date:			Edition 2

Approval Signatures

Author:	Date: 01-04-19
Quality Control:	Date: 01-04-19
Quality Assurance:	Date: 01-04-19

To be filled out by Requestor:

Item #	Part #	Lot #	Current Exp. Date	Requested By Date
1	GtxHu-014-D	4-186-101107	March, 7, 2020	07-30-19
2				
3				
4				

Requestor/Date: AS 07-30-19

To be filled out by QA:

Item #	Results	Old Rev. #	New Rev. #
1	Pass or Fail	7	8
2	Pass or Fail		
3	Pass or Fail		
4	Pass or Fail		

C of A Reviewed

Sign/Date 07/31/19

Action	Init/Date
✓ Prepare QC Aliquot	VPA 07-31-19
✓ QCF 3073 Attached	VPA 07-31-19
o New C of A Revised	CDS 07-31-19
• **Final QC Sign Off**	
• **Insert Rev #**	
• **Update Expiration Date**	
o C of A Transferred/ Old C of A Archived	CDS 07-31-19

Testing Required to Extend Expiration Dates

Test	Init/Date
SDS-PAGE	VPA 07-31-19
IEP	NIA ①
ELISA/FLISA	
FIT	
HPLC	VPA 07-31-19
Other: NIA ①	NIA ①

o Documents Scanned
Init/Date UR 08-28-19

① VPA 07-31-19

ImmunoReagents Inc.	Quality Control Form (QCF)		Page 1 of 3
	Form:	QCF # 3073	
	Title:	How to Assign Expiration Dates to Products	

Document Effective Date: January 10th, 2019	Edition 5

Approval Signatures

Author:	Date: 01-07-19
Quality Control:	Date: 01-07-19
Quality Assurance:	Date: 01-10-19

Materials:

Item #	Part #	Lot #
1	GtxHu-014-D	4-186-101107
2		
3	N/A ①	
4		

Procedure:

1. Prepare product sample and run an SDS-PAGE as per QCP # 3000.

QCF # 3000 is located:

Item #	Binder #	Packet #	Lane #
1	3	98	2/4
2			
3	N/A ①		
4			

Init/Date: VPA 07-31-19

Attach a copy of the labeled SDS-PAGE image scan to the back of QCF # 3073.

Init/Date: VPA 07-31-19

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① VPA 07-31-19

2. Comparison of the original SDS-PAGE to the current SDS-PAGE indicates:

A. Product bands show no change from original.

Item #	Yes	No
1	✓	
2		
3		
4		

N/A CDS 07-31-19

If yes, proceed to step 4.

B. Product bands show evidence of degradation based on the original SDS-PAGE.

Item #	Yes	No
1		✓
2		
3		
4		

N/A CDS 07-31-19

If yes, proceed to step 3.

Init/Date: CDS 07-31-19

3. If degraded, proceed to SOP # 2046, Procedure for Disposition of Failed Product. Attach completed DCF # 2046 to the current QCF # 3073.

Init/Date: N/A CDS 07-31-19

4. If the new SDS-PAGE shows that the product(s) has/have no evidence of degradation, then assign a new expiration date. The product(s) expiration date will be two years from the date of QC release.

New Expiration Date: 07-31-21

Init/Date: CDS 07-31-19

5. Revise the Certificate of Analysis to reflect the new expiration date for the product(s).

Init/Date: CDS 07-31-19

6. Complete QCF #3073 and file with the product(s) original MPBR.

Init/Date: CDS 07-31-19

Scientist/Date: Vee Ort 07.31.19

Quality Assurance/Date: 07-31-19

Revision History:

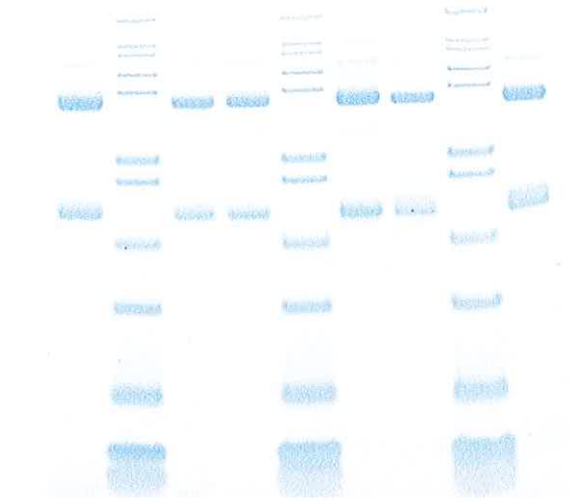
Edition #	Author	Significant Changes	Effective Date
005	Chris Johnson	Expanded to 4 product Re-QC's. No CAPA initiation for failed Re-QC Product. Quality Assurance signature required instead of Quality Control.	01-10-19

Attachment A1
VPA 07.31.19

SDS-PAGE

Binder 3, Packet 98 Labeled

1	2	3	4	5	6	7	8	9	10
N/A	GtxHu-014-D, 4-186-101107, 3.0 µg	MWM	GtxHu-014-D, 4-186-101107, 1.5 µg	GtxHu-025-D, 9-60-100708, 1.5 µg	MWM	GtxHu-025-D, 9-60-100708, 3.0 µg	GtxHu-075-D, 31-60-121012, 1.5 µg	MMW	GtxHu-075-D, 31-60-121012, 3.0 µg

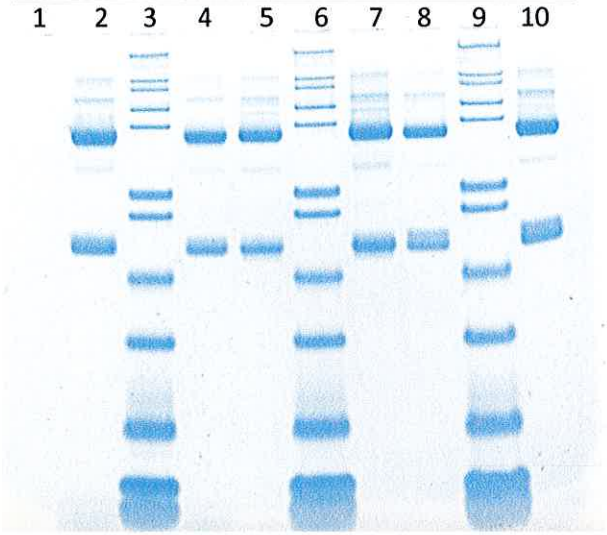


Attachment A2
VPA 07319

SDS-PAGE

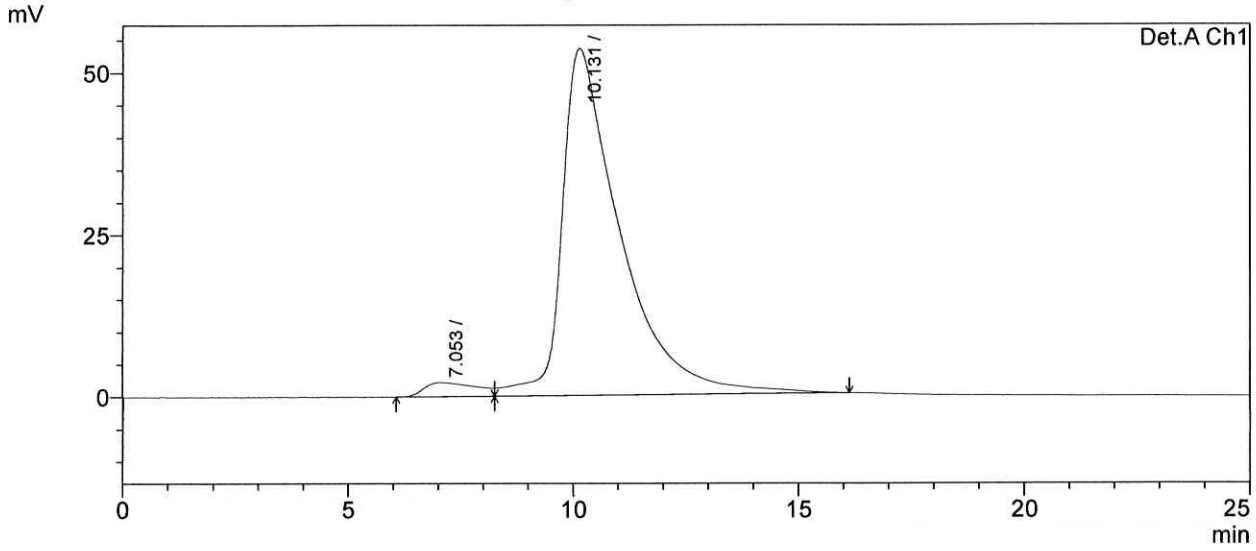
Binder 3, Packet 98 Labeled Lens

1	2	3	4	5	6	7	8	9	10
N/A	GtxHu-014-D, 4-186-101107, 3.0 µg	MWM	GtxHu-014-D, 4-186-101107, 1.5 µg	GtxHu-025-D, 9-60-100708, 1.5 µg	MWM	GtxHu-025-D, 9-60-100708, 3.0 µg	GtxHu-075-D, 31-60-121012, 1.5 µg	MMW	GtxHu-075-D, 31-60-121012, 3.0 µg



Sample Name	: GtxHu-014-D 4-186-101107
Sample ID	: GtxHu-014-D 4-186-101107
Injection Volume	: 20 uL
Data File Name	: GtxHu-014-D 4-186-101108.lcd
Method File Name	: SEC 20ul Loop MAB PAC.lcm
Batch File Name	:
Report File Name	: SEC 20ul Loop Report.lcr
Data Acquired	: 7/31/2019 8:30:17 AM
Data Processed	: 7/31/2019 8:55:19 AM

C:\LabSolutions\Data\Project1\GtxHu-014-D 4-186-101108.lcd



1 Det.A Ch1/280nm

PeakTable

Detector A Ch1 280nm

Peak#	Ret. Time	Area	Height	Area %	Name
1	7.053	178332	2169	3.570	
2	10.131	4817224	53529	96.430	
Total		4995555	55699	100.000	

GPC Results

Certificate of Analysis

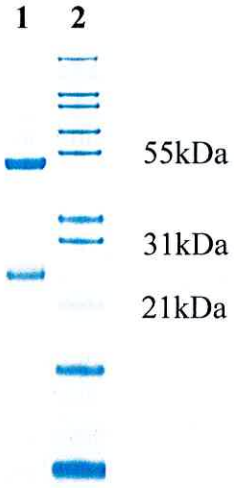
Product:	Goat anti-Apolipoprotein A1, Affinity Pure
Part Number:	GtxHu-014-D
Lot Number:	4-186-101107
Concentration:	3.53 mg/ml ($E^{1\%}$ at 280 nm = 13.0)
Amount:	1.0 mg
Form:	Clear, colorless liquid, 0.2 µm filtered
Purification:	Affinity purified using solid-phase Human Apolipoprotein A1
Purity:	≥ 95 % based on SDS-PAGE: Based on IEP, this antibody provides a single arc in the gamma region when reacted against: • anti-Goat whole serum • anti-Goat IgG
Host:	Goat
Immunogen:	Purified Human Apolipoprotein A1
Buffer:	10 mM Sodium Phosphate, 0.15 M Sodium Chloride, pH 7.2
Preservative:	0.05 % (w/v) Sodium Azide
Storage:	2-8 °C
Expiration Date:	July 31, 2021
Specificity:	Based on IEP, this antibody reacts as a single arc in the alpha region against: • whole Human serum • Human Apolipoprotein A1
Country of Origin:	Goat serum was obtained from healthy animals of US origin and under the care of a registered veterinarian.
Applications:	Suitable for use in: ELISA, WB, IHC, ICC, CL, FACS, IM, IF The optimal working dilution should be determined by the investigator.
Disclaimer:	*For in vitro Laboratory Use Only.* Not for diagnostic or therapeutic use. Not for human or animal consumption. The proper selection and use of our products is the sole responsibility of the end user, and therefore we can offer no guarantee to a specific experimental outcome. Suggested applications of our products are not recommendations to use our products in violation of any patent or as a license under any patent of ImmunoReagents, Inc. **Product may not be resold or modified for resale without prior written approval of ImmunoReagents, Inc.**

Testing Results

PRODUCT: Goat anti-Apolipoprotein A1, Affinity Pure
PART NUMBER: GtxHu-014-D
LOT NUMBER: 4-186-101107

TESTS	SPECIFICATIONS	RESULTS
Appearance:	Clear, colorless liquid	PASS
Purity:	Two predominant bands at 50 and 24 kDa based on SDS-PAGE	PASS
	Based on IEP, this antibody reacts as a single arc in the gamma-region when 5 µg of antibody is reacted with:	
	• 100 µl of anti-Goat whole serum	PASS
	• 100 µl of anti-Goat IgG	PASS
Specificity:	Based on IEP, this antibody reacts as a single arc in the alpha region when 100 µg of antibody is reacted with:	
	• 5 µl whole Human serum	PASS
	• 5 µg of high purity Human Apolipoprotein A1	PASS

SDS-PAGE



1) GtxHu-014-D, Lot # 4-186-101107
2) Mol Weight Standard

Date: July 31, 2019

Signature: _____
Quality Control

Rev.8 073119CDJ