Negative Diluent Evaluation Pack
1800-0068

INTENDED USE
The Negative Diluent Evaluation Pack includes a variety of LGC SeraCare's off the shelf diluents, such as SeraCon™, Basematrix, and pooled human serum. These products are cost-effective, human blood-based matrices that are ideal for quality control and diagnostics development solutions. This material is well suited for use as diluents in the development of IVD assays, preparing controls and calibrators, and to support research and development. Sample our variety of plasma products to determine which will satisfy your clinical diagnostic applications. For research use only. Not for use in diagnostic procedures.

PRODUCT DESCRIPTION
The Negative Diluent Evaluation Pack is comprised of 9 different formulated human plasma products. All of the diluents included in the evaluation pack have been tested and found negative for HBsAg and antibodies to HCV and HIV-1/2 by FDA approved methods.

Material Number: 1800-0068, 9 bottles
8 x 100 mL, 1 x 50 mL

STORAGE
Store these products frozen at -20 °C or colder. Once thawed and opened, bottles should not be reused. Alterations in physical appearance may indicate instability or deterioration of diluents. Solutions that are visibly turbid should be discarded.

LIMITATIONS
The products included in the Negative Diluent Evaluation Pack are offered for research use only. Not for use in diagnostic procedures.

PRECAUTIONS
These materials have not been treated and should be considered biohazardous. Follow Universal Precautions[1]. The products included in the Negative Diluent Evaluation Pack have been tested and found negative for HBsAg and antibodies to HCV and HIV-1/2 by FDA approved methods.

Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

These materials should be disposed of in a manner that will inactivate pathogenic agents.

Table 1. Diluents Included in Evaluation Pack

Product	Material #	Volume
SeraCon I Negative Diluent	1800-0008	100 mL
SeraCon II Negative Diluent	1800-0011	100 mL
SeraCon II D Lipid Depleted Negative Diluent	1800-0016	100 mL
SeraCon Matribase Negative Diluent	1800-0022	100 mL
SeraCon II CD Hormone Depleted Negative Diluent	1800-0026	100 mL
SeraCon Vitamin D Depleted Negative Diluent	1800-0049	100 mL
SeraCon II CD Hormone Depleted Double-Stripped Negative Diluent	1800-0057	100 mL
Pooled Human Serum	1830-0002	100 mL
Basematrix Negative Diluent	1805-0076	50 mL

REFERENCES
1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

For assistance, contact LGC SeraCare at 508.244.6400.

The package insert for this panel can be found at www.seracare.com.

A printed copy of the package insert or data sheet may be requested by email at CDx-Info@LGCGroup.com or by phone at 508.244.6400.

Certificate of Analysis

Product Description:	SeraCon™ I, Defibrinated Normal Human Plasma		
Material Number:	1800-0008, 1800-0009, 1800-0052, 1800-0063	Batch:	10521511
Storage:	-20°C	Manufacture Date:	08 OCT 2020

Analyte	***Results***	
Albumin	3.5	g/dL
Calcium	76	mg/dL
Cholesterol	142	mg/dL
Triglyceride	191	mg/dL
BUN	13.6	mg/dL
Creatinine	0.9	mg/dL
Glucose	659.2	mg/dL
T. Protein	5.4	g/dL
Uric Acid	3.4	mg/dL
Sodium	165	mEQ/L
Potassium	3.6	mEQ/L
Chloride	117	mEQ/L
Phosphorus	7.1	mg/dL
pH	7.3	
Bioburden	0	cfu/mL

This product was manufactured from human plasma and each donor was tested by an FDA approved method for the presence of antibody to HIV 1/2, antibody to HCV, HIV-Ag and/or HIV NAT, HCV NAT, as well as for HBsAg, and found to be negative.

In addition, each donor and/or donor unit was tested for Syphilis and found to be negative.

Approval:

19 OCT 2020

Prepared By — Date

19 OCT 2020

QA Verified By — Date

Certificate of Analysis

Product Description:	SeraCon™ II, Defibrinated Human Plasma		
Material Number:	1800-0002,1800-0011,1800-0012	Batch:	10586811
Storage:	-20°C	Manufacture Date:	05 NOV 2021

	Analyte	Result		Assay Lower Limit
	Albumin	3.9	g/dL	
	Calcium	11	mg/dL	
	Cholesterol	154	mg/dL	
	Triglycerides	110	mg/dL	
	BUN	1.0	mg/dL	
**	Creatinine	0.1	mg/dL	<0.17 mg/dL
	Glucose	28.8	mg/dL	
	Total Protein	6.2	g/dL	
	Uric Acid	0.3	mg/dL	
	Sodium	105	mEq/L	
	Potassium	4.8	mEq/L	
	Chloride	81	mEq/L	
	Phosphorus	1.2	mg/dL	
	pH	7.1		
	Bioburden	0	CFU/mL	

** Reported test result is below lower limit of assay linearity

This product has been 0.2µm filtered with no preservatives added.

Each donor unit and the final product were tested by FDA approved methods and found to be negative for the presence of HBsAg and antibodies to HCV and HIV 1/2.

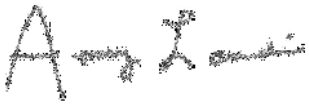
In addition, each donor unit was tested by an FDA approved method and found to be negative for the presence Syphilis.

Certificate of Analysis

Product Description:	SeraCon™ II, Defibrinated Human Plasma		
Material Number:	1800-0002,1800-0011,1800-0012	Batch:	10586811
Storage:	-20°C	Manufacture Date:	05 NOV 2021

All blood-based material should be handled as potentially biohazardous. For laboratory research or further manufacture into *in-vitro* diagnostic reagents for which there are no alternative sources.

Approval:



16 NOV 2021

Prepared By — Date

17 NOV 2021

QA Verified By — Date

Certificate of Analysis

Product Description:	SeraCon™ II, Delipidated Normal Human Plasma		
Material Number:	1800-0003, 1800-0016, 1800-0017	Batch:	10646139
Storage:	-20°C	Manufacture Date:	22 DEC 2022

	Analyte	Results		Assay Lower Limit
	Albumin	4.1	g/dL	
*	BUN	0.4	mg/dL	<1.4
	Calcium	8	mg/dL	
	Chloride	81	mEq/L	
*	Cholesterol	2	mg/dL	<3.86
*	Creatinine	0.1	mg/dL	<0.17
	Glucose	10.3	mg/dL	
	Phosphorus	1.2	mg/dL	
	Potassium	5.0	mEq/L	
	Sodium	108	mEq/L	
	Total Protein	6.4	g/dL	
*	Triglycerides	5	mg/dL	<8.85
*	Uric Acid	0.1	mg/dL	<0.2
	pH	7.4		
	Bioburden	0	CFU/mL	

* Reported test result is below lower limit of assay linearity

This product was manufactured from human plasma and is defibrinated and 0.2 µm filtered.

Each donor unit was tested by FDA approved methods and found to be negative for the presence of HBsAg, HIV NAT, and antibodies to HCV and HIV 1/2. In addition, each donor and/or donor unit was tested for Syphilis and found to be negative.

All blood-based material should be handled as potentially biohazardous. For laboratory research or further manufacture into in-vitro diagnostic reagents for which there are no alternative sources.

Approval:

Prepared By — Date: 09 JAN 2023

QA Verified By — Date: 10 JAN 2023

Certificate of Analysis

Product Description:	SeraCon Matribase		
Material Number:	1800-0005, 1800-0022	Batch:	10658632
Storage:	-20°C	Manufacture Date:	02 MAR 2023

	Analyte	Results		Assay Lower Limit
	Albumin	5.2	g/dL	
**	Calcium	0.1	mg/dL	< 0.8 mg/dL
**	Cholesterol	0.0	mg/dL	< 3.86 mg/dL
**	Triglyceride	3.2	mg/dL	< 8.85 mg/dL
**	**BUN	0.5	mg/dL	< 1.4 mg/dL
**	Creatinine	0.0	mg/dL	< 0.17 mg/dL
	Glucose	105	mg/dL	
	T. Protein	5.9	g/dL	
**	Uric Acid	0.0	mg/dL	< 0.2 mg/dL
	Sodium	137	mEQ/L	
	Potassium	4.8	mEQ/L	
	Chloride	120	mEQ/L	
**	Phosphorous	0.0	mg/dL	< 0.31 mg/dL
	pH	7.2		
	Bioburden	0	CFU/mL	

**Reported test result is below the lower limit of assay linearity

Each donor unit was tested by FDA approved methods and found to be negative for the presence of HBsAg, HIV NAT, and antibodies to HCV and HIV 1/2. In addition, each donor and/or donor unit was tested for Syphilis and found to be negative.

All blood-based material should be handled as potentially biohazardous. For laboratory research or further manufacture into *in-vitro* diagnostic reagents for which there are no alternative sources.

Approval:

	13 MAR 2023
Prepared By	Date
	13 MAR 2023
QA Verified By	Date

Certificate of Analysis

Product Description:	SeraCon™ II, Defibrinated, Stripped, Delipidated, Normal Human Plasma		
Material Number:	1800-0006,1800-0026,1800-0027	Batch:	10634958
Storage:	-20°C	Manufacture Date:	07 OCT 2022

	Analyte	Results		Assay Lower Limit
	Albumin	4.2	g/dL	
**	BUN	1.0	mg/dL	< 1.4 mg/dL
	Calcium	9	mg/dL	
	Chloride	81	mEq/L	
**	Cholesterol	3	mg/dL	< 3.86 mg/dL
	Creatinine	0.3	mg/dL	
**	Glucose	0.0	mg/dL	< 2 mg/dL
	Phosphorus	1.9	mg/dL	
	Potassium	4.6	mEq/L	
	Sodium	106	mEq/L	
	Total Protein	6.4	g/dL	
**	Triglycerides	4	mg/dL	< 8.85 mg/dL
**	Uric Acid	0.0	mg/dL	< 0.2 mg/dL
	pH	7.2		
	Bioburden	0	cfu/mL	
	Cortisol	0.27	µg/dL	
	T4	0.13	µg/dL	

** Reported test result is below lower limit of assay linearity

This product was manufactured from human plasma, and each donor unit was tested by FDA approved methods and found to be negative for the presence of HBsAg and antibodies to HCV, HIV 1/2 and HIV NAT. In addition, each donor and/or donor unit was tested for Syphilis and found to be negative.

All blood-based material should be handled as potentially biohazardous. For laboratory research or further manufacture into *in-vitro* diagnostic reagents for which there are no alternative sources.

Approval:

14 OCT 2022

Prepared By — Date

17 OCT 2022

QA Verified By — Date

Certificate of Analysis

Product Description:	SeraCon, Vitamin D Depleted Diluent		
Material Number:	1800-0049, 1800-0050, 1800-0051	Batch:	10671974
Storage:	-20°C	Manufacture Date:	20 JUL 2023

	Analyte	Results		Assay Lower Limit
	Vitamin D_2 *by LCMS/MS*	< 1 ng/mL	ng/mL	
	Vitamin D_3 *by LCMS/MS*	< 1 ng/mL	ng/mL	
	Total D_2/D_3 *by LCMS/MS*	< 2 ng/mL	ng/mL	
	Total Vitamin D *by Immunoassay*	< 8 ng/mL	ng/mL	
	Albumin	3.9	g/dL	
	Calcium	5	mg/dL	
	Cholesterol	128	mg/dL	
	Triglyceride	84	mg/dL	
**	BUN	0.3	mg/dL	(<1.4)
**	Creatinine	0.0	mg/dL	(<0.17)
**	Glucose	0.2	mg/dL	(<2)
	T. Protein	5.9	g/dL	
**	Uric Acid	0.0	mg/dL	(< 0.2)
	Sodium	105	mEQ/L	
	Potassium	4.9	mEQ/L	
	Chloride	82	mEq/L	
**	Phosphorus	0.2	mg/dL	(< 0.31)
**	Fibrinogen	8	mg/dL	(< 12.0)
	pH	7.3		
	Bioburden	0	CFU/mL	

This product was manufactured from human plasma, and each donor unit used was tested by an FDA approved method for the presence of antibody to HIV 1/2, antibody to HCV, as well as for HBsAg and found to be negative.

All blood-based material should be handled as potentially biohazardous. For laboratory research or further manufacture into in-vitro diagnostic reagents for which there are no alternative sources.

Approval:

Prepared By	28 JUL 2023 Date
QA Verified By	28 JUL 2023 Date

Certificate of Analysis

Product Description:	SeraCon™II, Double Stripped, Delipidated Normal Human Plasma		
Material Number:	1800-0035, 1800-0057, 1800-0058, 1800-0066	Batch:	10635772
Storage:	-20°C	Manufacture Date:	12 OCT 2022

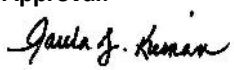
	Analyte	Results		Assay Lower Limit
	Albumin	4.3	g/dL	
	Calcium	8	mg/dL	
**	Cholesterol	1	mg/dL	< 3.86 mg/dL
**	Triglyceride	8	mg/dL	< 8.85 mg/dL
	BUN	1.4	mg/dL	
**	Creatinine	0.1	mg/dL	< 0.17 mg/dL
	Glucose	47.6	mg/dL	
	T. Protein	6.4	g/dL	
**	Uric Acid	0.0	mg/dL	<0.2 mg/dL
	Sodium	120	mEq/L	
	Potassium	4.7	mEq/L	
	Chloride	93	mEq/L	
	Phosphorus	2.5	mg/dL	
	Cortisol	0.0	µg/dL	
	T4	0.16	µg/dL	
	Bioburden	0	cfu/mL	
	pH	7.3		

** Reported test result is below lower limit of assay linearity

This product was manufactured from recovered human plasma, and each donor unit used was tested by an FDA approved method for the presence of antibody to HIV 1/2, antibody to HCV, as well as for HBsAg, and found to be negative.

In addition, each donor and/or donor unit was tested for Syphilis and found to be negative.

Approval:



19 OCT 2022

Prepared By — Date

19 OCT 2022

QA Verified By — Date

Certificate of Analysis

Product Description:	Pooled True Human Serum		
Material Number:	1830-0005, 1830-0003, 1830-0002	Batch:	10634976
Storage:	-20°C	Manufacture Date:	07 SEP 2022

Analyte	Results	
Albumin	4.5	g/dL
Calcium	9.5	mg/dL
Cholesterol	186.4	mg/dL
Triglyceride	146	mg/dL
BUN	15.7	mg/dL
Creatinine	1.0	mg/dL
Glucose	70	mg/dL
T. Protein	6.9	g/dL
Uric Acid	5.4	mg/dL
Sodium	140	mEq/L
Potassium	7.1	mEq/L
Chloride	100	mEq/L
Phosphorus	3.9	mg/dL
pH	7.91	
Bioburden	0	cfu/mL

This product was manufactured from pooled human serum, and each sample used was tested by an FDA approved method for the presence of antibody to HIV 1/2, antibody to HCV, HIV NAT, Syphilis and HBsAg, and found to be negative.

In addition, the finished product was tested by FDA approved methods for the presence of antibody to HIV-1/2, antibody to HCV, and HBsAg and found to be negative.

Approval:

	12 SEP 2022
Prepared By	Date
	13 SEP 2022
QA Verified By	Date

Certificate of Analysis

Product Description:	Basematrix 53, Defibrinated Human Plasma		
Material Number:	1805-0075, 1805-0076	Batch:	10680295
Storage:	-20°C	Manufacture Date:	17 AUG 2023

Analyte	Results	
Chloride	96	mEQ/L
Cholesterol	138	mg/dL
Phosphorus	2.9	mg/dL
Potassium	3.6	mEQ/L
Sodium	149	mEQ/L
Total Protein	5.5	g/dL
Triglycerides	70	mg/dL
pH	7.2	
Bioburden	0	CFU/mL

Basematrix 53 is a processed defibrinated human plasma product manufactured from plasma collected at US FDA licensed centers.

Basematrix 53 has been filtered through 0.2 µm filters, frozen at -20°C or below and does not contain any preservative. The product should be kept frozen at -20°C or below until use. Slight turbidity is a common result of the freeze thaw process. Filtration can be used to clarify the product.

Each donor unit was tested by FDA approved methods and found to be negative for the presence of HBsAg, HIV RNA, and antibodies to HCV and HIV 1/2. In addition, each donor and/or donor unit was tested for Syphilis and found to be negative.

The finished product was tested by FDA approved methods and found to be negative for the presence of HBsAg, HIV RNA, HCV RNA, HBV DNA, and antibodies to HCV, HIV 1/2, HBc, and HTLV I/II.

Approval:

Prepared By	31 AUG 2023 Date
QA Verified By	31 AUG 2023 Date