中国认可
国际互认
检测
TESTING
CNAS L 10463

Test Report

Report Number: 25111081-03-R02EN

Sponsor: Changzhou Dreure Medical Material Co.,Ltd.

Factory: Changzhou Dreure Medical Material Co.,Ltd.

Sample Name: Ultra Clean Autoclave Bag/ Roll Bag

Model/ Specification: /

Test Category: Commission Test

EPINTEK Suzhou Ltd.

苏州爱碧质量技术服务有限公司 检验检测专用章

Declaration

1. The report is invalid without the special stamp for test report of the test facility.
2. Partial copy is invalid without written approval of the test facility.
3. Any copy is invalid without the special stamp of the test facility for test report.
4. The report is invalid without the signature of the authorized signatory.
5. The report is invalid once altered.
6. Any comment to the report should be submitted in writing to the test facility, otherwise it may not be accepted.
7. The results in this report are relevant only to the articles tested.
8. The sponsor is responsible for the authenticity of the sample and its information.

Institution name: EPINTEK Suzhou Ltd.

Address: Floors 1-3, West side of Building A2; Floors 1-4, Building 4; Floor 5, Building 3. No. 558, Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

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Postal Code: 215211

EPINTEK Suzhou Ltd.
Test Report

Report Number: 25111081-03-R02EN

Sample Name	Ultra Clean Autoclave Bag/ Roll Bag	Sample ID	25111081-S001
Model/ Specification	/		
Sponsor	Changzhou Dreure Medical Material Co.,Ltd.		
Address	No.7 Jinhua Road, Wujin Economic Development Zone, Changzhou, Jiangsu, China.		
Factory	Changzhou Dreure Medical Material Co.,Ltd. / No.7 Jinhua Road, Wujin Economic Development Zone, Changzhou, Jiangsu, China.		
Test Facility	EPINTEK Suzhou Ltd.		
Test Category	Commission Test	Batch#	S20251114
Produced Date	/	Sample Quantity	8 PCS
Received Date	2025-11-17	Test Date(s)	2025-12-01 to 2025-12-04
Test Item(s)	In Vitro Hemolytic properties Test (ASTM method)		
Test Method(s)	ISO 10993-4: 2017 Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood		
Conclusions	Under the conditions of this study, the hemolysis grade of the sample was nonhemolytic by both the direct method and the extraction method. (Stamp for Test Report) Issued Date: 2025-12-30		
Note	"NA" means "not applicable", "/" means "blank"		

Approved By: Look Lu

Look Lu

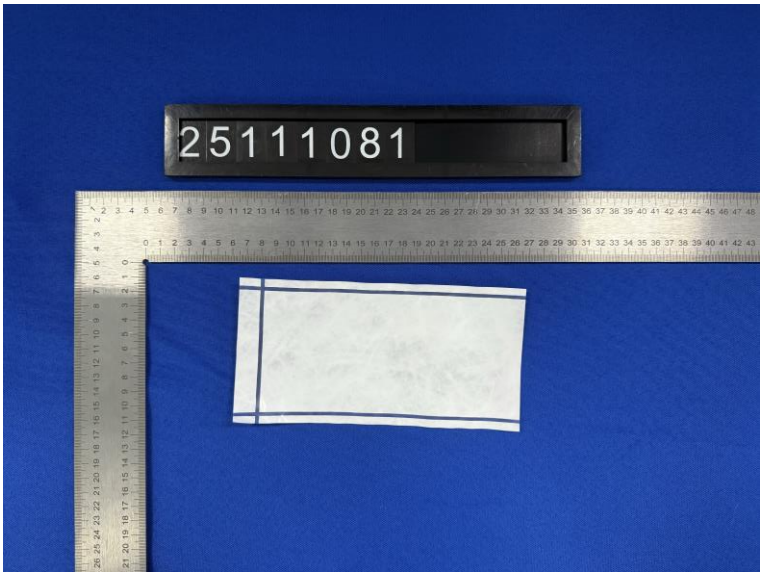
Position: Authorized Signatory

EPINTEK Suzhou Ltd.
Test Report

Report Number: 25111081-03-R02EN

No.	Item	Standard Method	Acceptance Criteria	Test Results	Conclusion	Note
1	In Vitro Hemolytic properties Test (ASTM method)	ISO 10993-4:2017	Hemolytic Index 0-2%, Nonhemolytic; Hemolytic Index 2-5% Slight hemolytic; Hemolytic Index >5% Hemolytic.	The results showed that the hemolytic index of direct contact was 0.71% and extract contact was 0.92%.	Nonhemolytic (Direct contact) Nonhemolytic (Extract contact)	Details shown in Annex 1
Following Blank						

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Picture & Introduction
 
Description for Sample, Model/Specification
Initial State: Unsterilized (Note: The information of sample hereby are provided by the sponsor.)
Misc
The laboratory random sampled according to the requirements of the sponsor.

Test Report

In Vitro Hemolytic properties Test (ASTM method)

Sponsor: Changzhou Dreure Medical Material Co.,Ltd.

Sample Name: Ultra Clean Autoclave Bag/ Roll Bag

Model/ Specification: /

Sample Amount for this test: 432.00 cm^2

Batch#: S20251114

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

The in vitro hemocompatibility testing was designed to evaluate if the test article Ultra Clean Autoclave Bag/ Roll Bag affected the hemolytic properties.

2. Process Description

Prepared a standard curve.
Obtain anti-coagulated rabbit blood from at least three donors. Approximately 5 mL should be drawn from each rabbit. Equal quantities of blood from each rabbit should be pooled. Adjust the total hemoglobin content of the blood sample to (10 ± l) mg/mL by diluting with an appropriate amount of calcium and magnesium-free PBS.
The extract group (including 3 tubes each of negative, positive, blank and sample) was treated at 50 ℃ for 72 h, and the direct contact group (including 3 tubes each of negative, positive, blank and sample) was added to diluted rabbit blood at a ratio of 1 mL diluted rabbit blood to 7 mL PBS at 37 ℃ for 3 h. The light absorption values were measured at 540 nm. The hemolysis rate was calculated.

3. Results

The text results showed that the hemolytic index of direct contact was 0.71% and extract contact was 0.92%.
The results of control groups showed the test was valid.

4. Conclusion

Under the conditions of this experiment, the hemolysis grade of the sample was nonhemolytic by both the direct method and the extraction method.

Edited by: Youhan Fu
Youhan Fu

Checked by: Hulda Tan
Hulda Tan

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Ultra Clean Autoclave Bag/ Roll Bag- In Vitro Hemolytic properties Test (ASTM method) (25111081-011254)

1.2. Purpose

The in vitro hemocompatibility testing was designed to evaluate if the test article affected the hemolytic properties.

1.3. Testing Facility

Name:	EPINTEK Suzhou Ltd.
Address:	Floors 1-3, West side of Building A2; Floors 1-4, Building 4; Floor 5, Building 3. No. 558, Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

1.4. Sponsor

Name:	Changzhou Dreure Medical Material Co.,Ltd.
Address:	No.7 Jinhua Road, Wujin Economic Development Zone, Changzhou, Jiangsu, China.
ATTN:	Wenqing Shi
Contact Information:	+86 152 9518 5667 / wenqing.shi@dreure.com

1.5. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.6. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a deviation report should be submitted with the TEST REPORT to interpretative the specific effect(s) on the final result caused by the deviation or incident.

1.7. Major Laboratory Personnel(s)

Study Director:	Hulda Tan
Main Operation Personnel:	Caya Chao, Positive Xu

1.8. Schedule of the Study

Protocol Effective Date:	/
Test Start Date:	2025-12-01
Test Completion Date:	2025-12-04
Report Completion Date:	2025-12-23

2. TEST INFORMATION

2.1. Blank Control

Name:	PBS (calcium- and magnesium-free)
Manufacturer:	SORFA
Lot/ Batch#:	S-0806
Size:	500 mL
Physical State:	Liquid
Color:	Colorless

2.2. Negative Control

Name:	High Density Polyethylene Film
Manufacturer:	Hatano Research Institute, FDSC
Batch#.:	C-212
Size:	c.a.3 cm×10 cm (5 sheets)
Physical State:	Solid
Color:	White
Storage Condition:	Room temperature
Extract Ratio:	3 cm^2: 1 mL

2.3. Positive Control

Name:	Nitrile gloves
Manufacturer:	Shanghai AMMEX Corporation
Batch#.:	0301
Size:	S
Physical State:	Solid
Color:	Blue
Storage Condition:	Room temperature
Extract Ratio:	6 cm^2: 1 mL

2.4. Main Instruments and Reagents

2.4.1. Main instruments

Name	No.	Calibration Due Date
Spectrophotometer	EPB-021	2026-08-12
Thermostatic water bath	EPB-445	2026-06-10

2.4.2. Main reagents

Name	Lot/ Batch#	Manufacturer
PBS (calcium- and magnesium-free)	S-0806	SORFA
Hemoglobin A, ferrous stabilized	SLVB6683	SIGMA
Brij®Lrs solution	SLCM9144	SIGMA
Drabkin's reagent	2023111417A	WengJiang Reagent

3. JUSTIFICATION OF THE TEST SYSTEM

Historically, rabbit blood have been used to evaluate the in vitro hemolytic properties of test article.

4. IDENTIFICATION OF TEST SYSTEM

Rabbit blood used in this test comes from New Zealand white rabbits.

5. ROUTE OF ADMINISTRATION

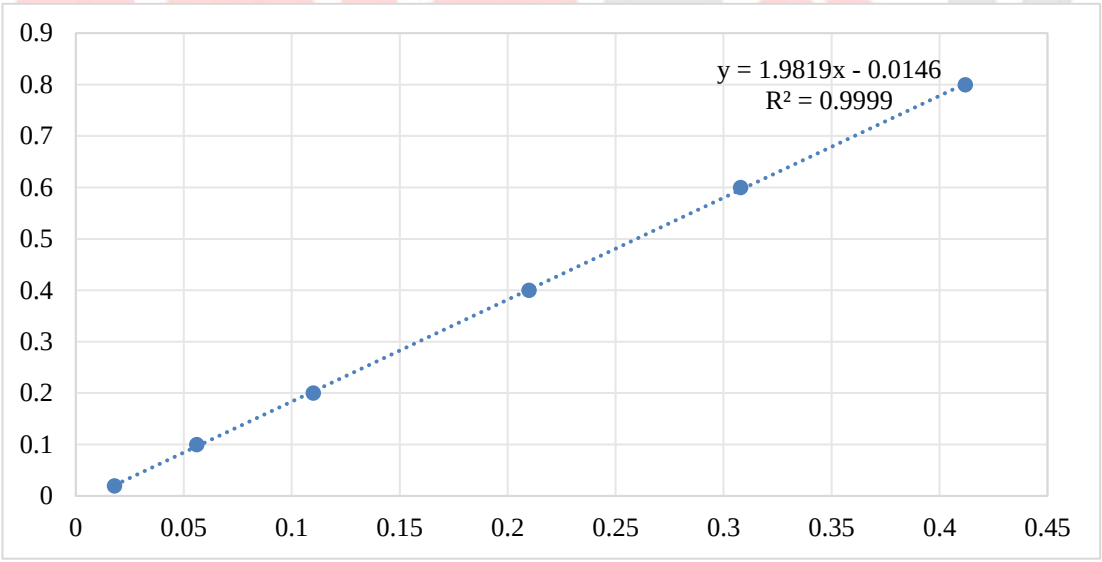
The test article and extract was administrated in vitro with the test system. This was the optimal route of administration available in this test system as recommended in the guidelines.

6. TEST DESIGN

6.1. Preparation Before Test

6.1.1. Prepared a standard curve

Took a Drabkin's reagent, added 1000 mL deionized water, then added 0.5 mL Brij®Lrs solution, prepared hemoglobin S solutions of different concentrations with the prepared solution, and measured the absorbance of hemoglobin S solution of 540 nm. A standard curve was established with absorbance as X-axis and hemoglobin concentration as Y-axis. The calibration coefficient F is the slope of the graph, and the intercept of y should be approximately 0.



y =1.9819x-0.0146

R^2=0.9999

y is the hemoglobin concentration (mg/mL) and x is the absorbance value

6.1.2. Blood

Obtain anti-coagulated rabbit blood from at least three donors. Approximately 5 mL should be drawn from each rabbit. Equal quantities of blood from each rabbit should be pooled.

6.1.3. Determination of plasma free hemoglobin concentration (PFH)

3 mL of whole blood was taken and centrifuged at 800 g for 15 min. 0.5 mL of plasma was mixed with 0.5 mL Drabkin's solution and stood at room temperature for 15 min. A^{PFH} was measured at 540 nm. The absorbance value was substituted into the standard curve to calculate free hemoglobin concentration (PFH) value.

$$PFH=A^{PFH}\times F\times 2$$

Table 1 Free hemoglobin concentration (PFH) value

	absorbance value (540 nm)	Hb（mg/mL）
Parallel 1	0.077	0.305
Parallel 2	0.074	0.293

PFH＜2 mg/mL, Continued to test.

6.1.4. Determination of Total Blood Hemoglobin Concentration (C)

Added 20 μL of well-mixed pooled whole blood to 5 mL Drabkin's solution, and stood at room temperature for 15 min. then the absorbance of the solution at 540 nm was read to obtain A^{C}. The absorbance value was substituted into the standard curve to calculate the whole blood hemoglobin concentration (C).

$$C=A^{C}\times F\times 251$$

6.1.5. Determination of blood dilution Hemoglobin Concentration (T)

Adjusted the total hemoglobin content of the blood sample to (10± l mg/mL) by diluting with an appropriate amount of calcium- and magnesium-free PBS. Used 300 μL of the diluted blood to 4.5 mL of Drabkin's reagent to remain on the standard curve. Then the absorbance of the solution at 540 nm was read to obtain A^{T}. The absorbance value was substituted into the standard curve to calculate the dilute blood hemoglobin concentration (T).

$$T=A^{T}\times F\times 16$$

Table 2 Dilute the blood absorbance value

absorbance value（540 nm）			Mean ± S
Parallel 1	Parallel 2	Parallel 3	
0.327	0.324	0.326	0.326 ±0.002

6.2. Testing Process

6.2.1. Extract Preparation of Extract Contact

Table 3 Extract process of extract contact

Group	Ratio	Sampling method	Actual sampling	Extracts	Extract Condition
Test	6 cm^2: 1 mL	Random[1)]	72.00 cm^2	12.00 mL	50℃, 72 h
			72.00 cm^2	12.00 mL	
			72.00 cm^2	12.00 mL	
Negative control	3 cm^2: 1 mL	Random	21.00 cm^2	7.00 mL	
			21.00 cm^2	7.00 mL	
			21.00 cm^2	7.00 mL	
Positive control	6 cm^2: 1 mL	Random	42.00 cm^2	7.00 mL	
			42.00 cm^2	7.00 mL	
			42.00 cm^2	7.00 mL	
Blank control	/	/	/	7.00 mL	
				7.00 mL	
				7.00 mL	

1） Took samples of the two materials in equal proportions.

Note: The final extract was used immediately. The extraction solution had no change after leaching in advance, and does not go through filtration, centrifugation, dilution, pH adjustment and other treatments before use.

For the above sample groups, 7.0 mL extraction solution was taken from each tube, and 1.0 mL diluted blood was added to each tube. For the other groups, 3.5 mL extraction solution was taken, and 0.5 mL diluted blood was added to each tube.

6.2.2. Extract Preparation of Direct Contact

Table 4 Extract process of direct contact

Group	Ratio	Sampling method	Actual sampling	Extracts	Diluted blood added
Test	6 cm^2: 1 mL	Random[1)]	72.00 cm^2	12.00 mL	1.72 mL
			72.00 cm^2	12.00 mL	1.72 mL
			72.00 cm^2	12.00 mL	1.72 mL
Negative control	3 cm^2: 1 mL	Random	21.00 cm^2	7.00 mL	1.00 mL
			21.00 cm^2	7.00 mL	1.00 mL
			21.00 cm^2	7.00 mL	1.00 mL
Positive control	6 cm^2: 1 mL	Random	42.00 cm^2	7.00 mL	1.00 mL
			42.00 cm^2	7.00 mL	1.00 mL
			42.00 cm^2	7.00 mL	1.00 mL
Blank control	/	/	/	7.00 mL	1.00 mL
				7.00 mL	1.00 mL
				7.00 mL	1.00 mL

1） Took samples of the two materials in equal proportions.

Table 3 and Table 4 All test tubes were bathed at 37℃ for 3 h; After centrifugation at 800 g for 15 min, 1.0 mL supernatant and 1.0 mL Drabkin's solution were taken and stood for 15 min. The absorption value was measured at 540 nm by spectrophotometer. Supernatant hemoglobin concentration was calculated.

7. DATA ANALYSIS

$$\text{Blank corrected hemolysis \%} = \frac{A^S - A^B}{A^T - A^B} \times 100\%$$

Notes: A^B = Blank absorbance value

A^T = Dilution blood absorbance value

A^S = Absorbance value of sample (negative and positive)

The results of the test samples were compared with the results of the negative control.

8. EVALUATION CRITERION

Hemolytic Index**(%)**	Hemolytic Grade
0-2	Nonhemolytic
2-5	Slight hemolytic
>5	hemolytic

- If the mean HI is less than 5, but one or more of the samples had an HI greater than 5, the experiment is repeated with double the number of samples.
- The HI value of the positive control must be ≥ 5%.

- The HI value of the negative control must be < 2%.

9. ALTERATION AND DEVIATION

No deviation affecting the validity of the test data occurred.

10. RESULTS

Result detail shown in Annex. A

11. CONCLUSION

Under the conditions of this experiment, the hemolysis grade of the sample was nonhemolytic by both the direct method and the extraction method.

12. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPINTEK Suzhou Ltd.

Annex. A

Table 5 Hemolytic Index

Extract contact									
Group	Absorbance 540 nm			Blank corrected % hemolysis			Blank corrected % hemolysis Mean	Hemolytic Index (%)	Conclusion
	Parallel 1	Parallel 2	Parallel 3	Parallel 1	Parallel 2	Parallel 3			
Test	0.004	0.005	0.005	0.92	1.23	1.23	1.13	0.92	nonhemolytic
Negative control	0.002	0.002	0.001	0.31	0.31	0.00	0.21	/	Preformed as expected
Positive control	0.319	0.321	0.323	97.95	98.56	99.18	98.56	98.35	Preformed as expected
Blank	0.001	0.001	0.002	0.00	0.00	0.31	0.10	/	Preformed as expected
Direct contact									
Group	Absorbance 540 nm			Blank corrected % hemolysis			Blank corrected % hemolysis Mean	Hemolytic Index (%)	Conclusion
	Parallel 1	Parallel 2	Parallel 3	Parallel 1	Parallel 2	Parallel 3			
Test	0.005	0.003	0.004	1.23	0.62	0.92	0.92	0.71	nonhemolytic
Negative control	0.002	0.001	0.002	0.31	0.00	0.31	0.21	/	Preformed as expected
Positive control	0.312	0.316	0.316	95.79	97.02	97.02	96.61	96.40	Preformed as expected
Blank	0.001	0.001	0.001	0.00	0.00	0.00	0.00	/	Preformed as expected

End of the Report