Clinical Study Report for Hemoglobin Test System (Whole Blood)

Ref.: OHBS-411

1. Purpose

The detection consistency and clinical application performance about the Hemoglobin Test System manufactured by Hangzhou AllTest Biotech. Co., Ltd. (abbreviated as AllTest) and the comparison product shall be evaluated by detection a certain numb Hemoglobin Test System is used for the quantitative detection of hemoglober of representative samples and analysis the result scientifically and reasonably.

2. Intended Use

In concentration in human capillary whole blood, venous whole blood.

3. Operation Procedures for Detection

3.1 Press "I/O" button to turn on the hemoglobin meter, insert the code chip printed the same code number with hemoglobin meter batch number. Ensure that the code number displayed on LCD of hemoglobin meter is confirm with the code number printed on code chip before start detection.

3.2 Open the hemoglobin test strip canister, take out one strip and insert the strip into the strip holder of meter with the arrow direction. When the add sample icon

" "appears on LCD, 10μl sample shall be dropped into the sample area of hemoglobin strip, the meter will start detection automatically.

3.3 The detection result will be displayed on LCD in 15 seconds. Remove the used test strip. The meter will return to ready for detection screen for another strip to be inserted and a detection to be performed.

4. Result Interpretation

Female Reference Interval: 120~150g/L（12.0~15.0g/dL,7.4~9.3mmol/L）
Male Reference Interval: 130~170g/L（13.0~17.0g/dL,8.1~10.5mmol/L）
Children Reference Interval: 110~140g/L（11.0~14.0g/dL,6.8~8.7mmol/L）

The decreasing of hemoglobin concentration is often caused by Anemia or bleeding-related diseases. hemoglobin concentration increasing is common in red blood cell proliferation.

5. Test Information

Test Product (Hemoglobin Test System from AllTest)：
Hemoglobin Test Strip from AllTest   Lot：HBS20110001-T
Hemoglobin Meter from AllTest   SN：HBM00000009-T
Comparison Product (Hemoglobin Test System from ACON)：
Hemoglobin Test Strip from ACON   Lot：201910125
Hemoglobin Meter from ACON   SN：195D0028AAE

POC: Dermatology Hospital of Guangxi Zhuang Autonomous Region

The Operators in POC:

Clinical Operator	Title	Responsibilities
Bangyong Zhu	Deputy Chief Inspector/Deputy Chief	Test Leader
Wei Li	Chief Physician/Associate Dean	Head of statistics and report
Jiangping Wei	Examiner	Clinical sample collection, test operator
Quan Gan	Examiner	Clinical sample collection, test operator

6. Clinical Sample Collection and Clinical Test Procedures

6.1 Clinical Sample Collection:

The Hemoglobin system is used for the quantity detection of the hemoglobin concentration in human capillary blood, venous blood. The sample shall be collected by operators according to the manuals of test product and comparison product. All operations need to be performed under the same conditions.

In order to protect the privacy of sample providers, the information such as name, gender about sample providers will not appear in test record.

6.2 Clinical Test Procedures

6.2.1 Operators in POC collect the sample (human capillary blood or venous blood) from sample providers, ten limit approached standard samples (five high value samples and five low value samples) are provided by Alltest, the two kinds of samples are numbered together.

6.2.2 Test Product: Hemoglobin Test System from AllTest

(1) POC operators detect the samples (contain limit approached standard samples) with Hemoglobin Test System from Alltest according to user manual.

(2) POC operators record the results.

6.2.3 Comparison Product: Hemoglobin Test System from ACON

(1) POC operators detect the samples (contain limit approached standard samples) with Hemoglobin Test System from ACON according to user manual.

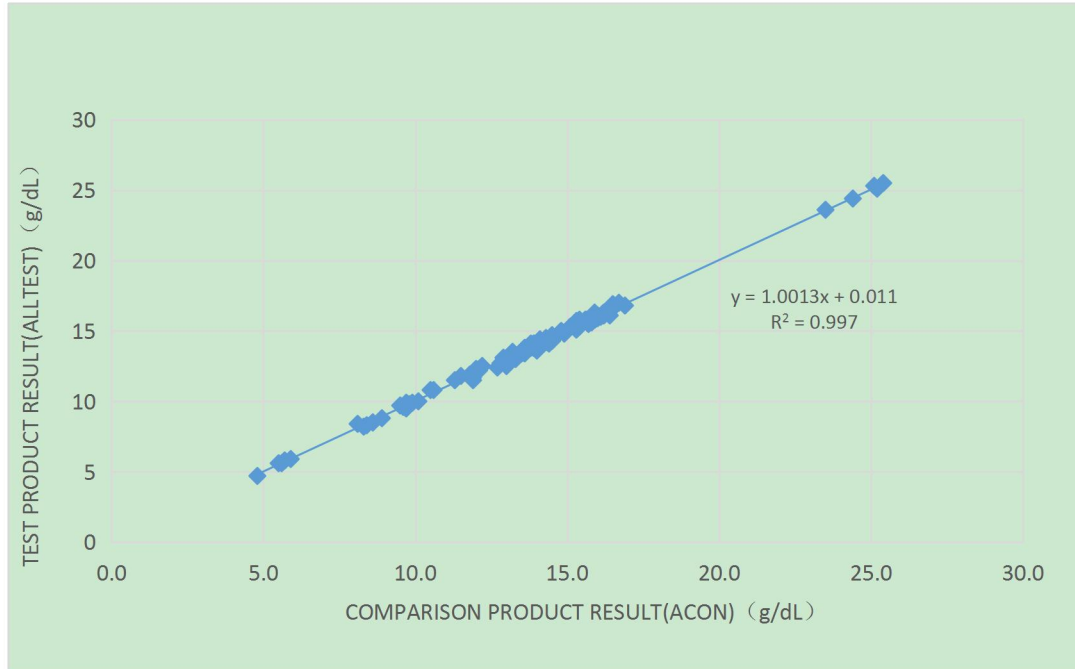(2) POC operators record the results.

7. Consistency Analysis (Regression Analysis)

The least square method is used to analyzed the results between two kinds of hemoglobin test systems from Alltest and ACON, and the correlation coefficient R value which is used for the judgment of consistency is obtained. The value of R is between 0 and 1, the closer the R value is to 1, the better the consistency between the results of the two test systems, when the R value is greater than 0.975, the consistency

is judged to be good.

8. Statistics of Clinical Results

According to test result in graph above，the R value of Hemoglobin Test System between AllTest and ACON is 0.998 (R^2=0.997).

9. Conclusion

115 samples (contain limit approached standard samples) have been tested in clinical test totally. According to the consistency analysis of test results, the correlation coefficient R value of Hemoglobin Test System between AllTest and ACON is 0.998 which indicates the high consistency, and the Hemoglobin Test System manufactured by AllTest can be applied in clinical hospitals for effective diagnosis of related diseases.

POC : Dermatology Hospital of Guangxi Zhuang Autonomous Region

Test Leader of POC (Signature):

Attachment 1

Sample No.	Hemoglobin Test System (AllTest) (g/dL)	Hemoglobin Test System (ACON) (g/dL)
0001	11.8	11.5
0002	14.7	14.5
0003	15.6	15.8
0004	9.5	9.7
0005	15.3	15.2
0006	15.5	15.7
0007	14.4	14.1
0008	14.4	14.5
0009	13.8	13.6
0010	13.4	13.6
0011	5.6	5.5
0012	14.3	14.5
0013	15.8	15.9
0014	14.3	14.5
0015	8.4	8.1
0016	9.9	9.7
0017	9.6	9.6
0018	11.5	11.9
0019	13.6	14.0
0020	4.7	4.8
0021	16.1	16.4
0022	16.3	15.9
0023	12.5	13.0
0024	16.2	15.9
0025	13.3	13.4
0026	15.8	15.9
0027	12.7	12.8
0028	15.5	15.7
0029	15.1	15.3
0030	12.4	12.7
0031	15.8	15.4
0032	15.3	15.1
0033	15.8	15.9
0034	23.6	23.5
0035	11.5	11.3
0036	12.9	13.0
0037	12.9	12.9
0038	14.1	13.9

0039	11.7	11.9
0040	15.9	15.9
0041	15.0	14.8
0042	15.3	15.4
0043	14.1	14.0
0044	15.8	15.7
0045	8.5	8.6
0046	10	10.1
0047	12.2	12.1
0048	12.2	12.0
0049	11.9	11.9
0050	11.9	11.8
0051	16.5	16.4
0052	13.1	12.9
0053	16.1	16.0
0054	15.6	15.7
0055	13.5	13.2
0056	16.1	16.2
0057	15.8	15.6
0058	15.9	16.0
0059	14.1	13.8
0060	11.9	11.8
0061	13.4	13.5
0062	13.4	13.2
0063	13.9	14.1
0064	12.5	12.2
0065	16.3	16.2
0066	15.1	15.3
0067	16	16.1
0068	14.2	14.3
0069	5.6	5.6
0070	8.5	8.6
0071	10.8	10.6
0072	25.1	25.2
0073	12.3	12.1
0074	12.1	12.0
0075	12.2	12.0
0076	5.8	5.7
0077	15.8	15.6
0078	16.1	16.2
0079	24.4	24.4

0080	25.3	25.1
0081	13.9	13.8
0082	14.1	13.9
0083	14.8	14.9
0084	14.5	14.3
0085	16.8	16.5
0086	14.1	14.0
0087	8.3	8.4
0088	9.9	9.9
0089	9.8	9.8
0090	12.5	12.2
0091	14.1	14.2
0092	16.9	16.5
0093	16.8	16.9
0094	16.4	16.4
0095	13.5	13.2
0096	5.9	5.9
0097	13.8	13.9
0098	10.8	10.5
0099	13.9	14.0
0100	25.5	25.4
0101	8.8	8.9
0102	15.4	15.4
0103	15.7	15.3
0104	14.0	14.1
0105	13.8	13.9
0106	13.5	13.2
0107	13.8	13.8
0108	14.1	14.4
0109	13	13.3
0110	17.0	16.7
0111	13.1	13.1
0112	8.2	8.3
0113	9.7	9.5
0114	9.5	9.7
0115	12.3	12.0