



Reproducibility Study Report for VivaDiag™ SARS-CoV-2 Ag Rapid Test

Document No.: TF025-005

Date of Issue: June 24, 2020

Ver1.0

1 Purpose

The purpose of this report is to confirm the reproducibility of VivaDiag™ SARS-CoV-2 Ag Rapid Test.

2 Scope

This report was applied to evaluate the reproducibility of the VivaDiag™ SARS-CoV-2 Ag Rapid Test.

3 References Document

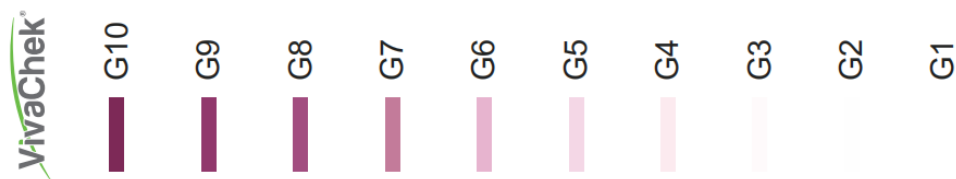
Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigen.

4 Responsibilities

R&D will be responsible for protocol preparation and testing.

5 Materials

- 5.1 Three (3) VivaDiag™ SARS-CoV-2 Ag Rapid Test Lot (Lot 1: T2006001, Lot 2: T2006002, Lot 3: T2006003)
- 5.2 Test Specimens
- 5.3 Color Grade (CF-0021-RE-02 Intensity Grading Card (Rev 0))



- 5.4 Dilute the Re-Ag with extraction solution to 0, 1, 8, 64 ng/mL and divide them into negative specimen, low positive specimen, moderately positive specimen and high positive specimen.

Table 1- Information of enterprise reference samples

Specimen	Concentration	Lot
N1	0 ng/mL	20200608-N1
P1	1 ng/mL	20200608-P1
P4	8 ng/mL	20200608-P4

P7	64 ng/mL	20200608-P7
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6 Methods

6.1 Test time and sites

Two sites (Technical Laboratory and R&D Center Laboratory) were selected and the test was conducted for five consecutive days.

6.2 Operators

The specimens are tested daily by 5 professional operators to evaluate the reproducibility in different operators.

Table 2 - Operators

No.	Operator
1	Michael Zhang
2	Leo Zhai
3	Aura Guo
4	Edison Song
5	Kane Ye

6.3 Test scheme

Each specimen repeatedly tests 10 times with 3 lots test device, and records the result

7 Acceptable criteria

T Line negative: $T < G3$; Positive: $T \geq G3$.

C Line: $\geq G8$.

Negative specimen (N1) should be tested negative.

Low positive specimen (P1) test results should range from G3 to G4.

Moderately positive specimen (P4) test results should range from G6 to G7.

High positive specimen (P7) test results should range from G9 to G10.

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8 Result

Test time	Day one											
Operator	1											
Specimen	N1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.4	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.5	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.6	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.7	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.8	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.9	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.10	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.11	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.12	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.13	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.14	G9	G1	G9	G1	G10	G2	G9	G1	G9	G1	G9	G1
Rep.15	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.16	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.17	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.18	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.19	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.20	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1

Test time	Day one											
Operator	2											
Specimen	N1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.4	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.5	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.6	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.7	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G10	G1
Rep.8	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.9	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.10	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.11	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.12	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.13	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.14	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.15	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.16	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.17	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.18	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.19	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.20	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1

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Test time	Day two											
Operator	3											
Specimen	N1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.4	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.5	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.6	G9	G1	G9	G1	G9	G1	G9	G2	G9	G1	G9	G1
Rep.7	G9	G1	G9	G1	G9	G2	G9	G1	G9	G1	G9	G1
Rep.8	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.9	G10	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.10	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.11	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.12	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.13	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.14	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.15	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.16	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.17	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.18	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.19	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.20	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1

Test time	Day two											
Operator	4											
Specimen	N1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.4	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.5	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.6	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.7	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.8	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.9	G9	G1	G9	G1	G10	G1	G9	G1	G9	G1	G9	G1
Rep.10	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.11	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.12	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G2
Rep.13	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.14	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.15	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.16	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.17	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.18	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.19	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.20	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1

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Test time	Day three											
Operator	5											
Specimen	N1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.2	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.3	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.4	G9	G1	G9	G1	G9	G1	G9	G1	G10	G1	G9	G1
Rep.5	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.6	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.7	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.8	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.9	G10	G1	G9	G2	G9	G1	G9	G1	G9	G1	G9	G1
Rep.10	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.11	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.12	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.13	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.14	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.15	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.16	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.17	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.18	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.19	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1
Rep.20	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1	G9	G1

Test time	Day one											
Operator	1											
Specimen	P1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.7	G9	G3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.11	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.12	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.13	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.14	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.15	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.16	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.17	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.18	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.19	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.20	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4

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Test time	Day one											
Operator	2											
Specimen	P1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.11	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.12	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.13	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.14	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.15	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.16	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.17	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.18	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.19	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.20	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4

Test time	Day two											
Operator	3											
Specimen	P1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G3	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.11	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.12	G9	G4	G9	G4	G9	G3	G9	G4	G9	G4	G9	G4
Rep.13	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.14	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.15	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.16	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.17	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.18	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.19	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.20	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4

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Test time	Day two											
Operator	4											
Specimen	P1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.7	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.11	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.12	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.13	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.14	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.15	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.16	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.17	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.18	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.19	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.20	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4

Test time	Day three											
Operator	5											
Specimen	P1											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.2	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.3	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.5	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.6	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.7	G9	G4	G9	G4	G9	G3	G9	G3	G9	G4	G9	G4
Rep.8	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.9	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.10	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.11	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.12	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.13	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.14	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.15	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.16	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.17	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.18	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.19	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4
Rep.20	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4	G9	G4

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Test time	Day one											
Operator	1											
Specimen	P4											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.2	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.3	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.5	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.7	G9	G6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.8	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.9	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.10	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.11	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.12	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.13	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.14	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.15	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.16	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.17	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.18	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.19	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.20	G9	G7	G9	G7	G9	G7	G9	G6	G9	G7	G9	G7

Test time	Day one											
Operator	2											
Specimen	P4											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.2	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.3	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.5	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.8	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.9	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.10	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.11	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.12	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.13	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.14	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.15	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.16	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.17	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.18	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.19	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.20	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7

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Test time	Day two											
Operator	3											
Specimen	P4											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.2	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.3	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.5	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.8	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.9	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.10	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.11	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.12	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.13	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.14	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.15	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.16	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.17	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.18	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.19	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.20	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7

Test time	Day two											
Operator	4											
Specimen	P4											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G7	G9	G7	G9	G7	G9	G6	G9	G7	G9	G7
Rep.2	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.3	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.5	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.8	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.9	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.10	G9	G6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.11	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.12	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.13	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.14	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.15	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.16	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.17	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.18	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.19	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.20	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7

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Test time	Day three											
Operator	5											
Specimen	P4											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.2	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.3	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.4	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.5	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.6	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.8	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.9	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.10	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.11	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.12	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.13	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.14	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.15	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.16	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.17	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.18	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.19	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7
Rep.20	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7	G9	G7

Test time	Day one											
Operator	1											
Specimen	P7											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G10	G9	G10	G9	G9	G9	G10	G9	G10	G9	G10
Rep.2	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.3	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.4	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.5	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.6	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.9	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.11	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.12	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.13	G9	G9	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.14	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.15	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.16	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.17	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.18	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.19	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.20	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10

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Test time	Day one											
Operator	2											
Specimen	P7											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G9
Rep.2	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.3	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.4	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.5	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.6	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.9	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.11	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.12	G9	G9	G9	G9	G9	G10	G9	G10	G9	G10	G9	G10
Rep.13	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.14	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.15	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.16	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.17	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.18	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.19	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.20	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10

Test time	Day two											
Operator	3											
Specimen	P7											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.2	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.3	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.4	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.5	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.6	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.9	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.11	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.12	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.13	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.14	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.15	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.16	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.17	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.18	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.19	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.20	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10

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Test time	Day two											
Operator	4											
Specimen	P7											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G10	G9	G10	G9	G10	G9	G9	G9	G10	G9	G10
Rep.2	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.3	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.4	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.5	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.6	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.9	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.11	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.12	G9	G10	G9	G9	G9	G10	G9	G10	G9	G10	G9	G10
Rep.13	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.14	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.15	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.16	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.17	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.18	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.19	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.20	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10

Test time	Day three											
Operator	5											
Specimen	P7											
Test site	Technical Laboratory						R&D Center					
Lot	T2006001		T2006002		T2006003		T2006001		T2006002		T2006003	
Results	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line	C Line	T Line
Rep.1	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.2	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.3	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.4	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.5	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.6	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.7	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.8	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.9	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.11	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.12	G9	G10	G9	G10	G9	G9	G9	G10	G9	G10	G9	G10
Rep.13	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.14	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.15	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.16	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.17	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.18	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.19	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10
Rep.20	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10	G9	G10

9 Conclusion

The test results show that the results of different operators meet the criteria.

Therefore, the repeatability meets the performance requirements.