



Sensitivity Study Report for VivaDiag™ COVID-19 Ag Rapid Test Device

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Ver1.0

1. Purpose

The purpose of this testing is to evaluate the limit of detection for VivaDiag™ COVID-19 Ag Rapid Test Device.

2. Scope

VivaDiag™ COVID-19 Ag Rapid Test Device.

3. References

CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline -Second Edition

Food and Drug Administration issued Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)

4. Responsibilities

R&D Team is responsible for testing.

5. Materials and Equipment

5.1 Three (3) VivaDiag™ COVID-19 Ag Rapid Test Device lots

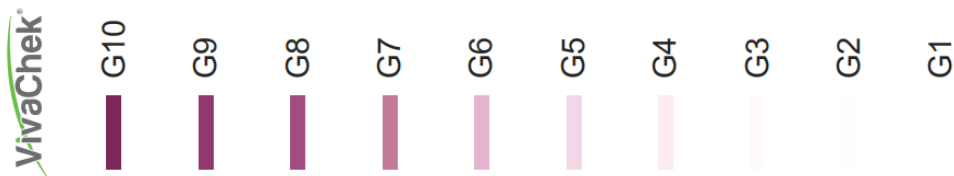
(Lot 1: T2006001, Lot 2: T2006002, Lot 3: T2006003)

5.2 One (1) Virus Culture Specimen (Inactivated)

5.3 Pipettes (S/N: 0633, S/N: 0634)

5.4 Timer (S/N: 0220)

5.5 Color Grade (CF-0021-RE-02 Intensity Grading Card (Rev 0))



6. Acceptance Criteria

6.1 Test Line

Negative results: $T < G3$

Positive results: $T \geq G3$

6.2 Limit of detection

The limit of detection is the antigen level of 95% or more positive detection rate.

7. Procedure

7.1 Study Site

The sensitivity study is conducted at the VivaChek Biotech (Hangzhou) Co., Ltd.

7.2 Sensitivity Study 1

The virus culture Specimen (Inactivated) make a serial dilution of 1:10, 1:100, 1:200, 1:400, 1:800, 1:1600, 1:3200, 1:6400, 1:12800 and 1:25600. Repeat 5 times to established a tentative LoD.

7.3 Sensitivity Study 2

Once a tentative LoD is established, the 1 virus culture Specimen (Inactivated) have a serial dilution of 1:3200, 1:6400 and 1:12800. Repeat 20 times to established LoD.

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8. Results

8.1 The virus culture Specimen Repeat 5 times to established a tentative LoD.

| Limit Of Detection | Virus Culture Specimen | | | | | | | | | | | |
|---|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--------|--------|
| Lot | T2006001 | | | | | | | | | | | |
| Sample | 1/10 | 1/100 | 1/200 | 1/400 | 1/800 | 1/1600 | 1/3200 | 1/6400 | 1/12800 | 1/25600 | | |
| Concentration in | 8.65x | 8.65x | 4.33x | 2.16x | 1.08x | 5.41x | 2.70x | 1.35x | 6.76x | 3.38x | | |
| Dilution tested(TCID ₅₀ /mL) | 10 ⁵ | 10 ⁴ | 10 ⁴ | 10 ⁴ | 10 ⁴ | 10 ³ | 10 ³ | 10 ³ | 10 ² | 10 ² | | |
| Test Sample | 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 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.2 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.3 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.4 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.5 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Postive rate % | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 4 | 0 |
| | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 80% | 0% |

| Limit Of Detection | Virus Culture Specimen | | | | | | | | | | | |
|---|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--------|--------|
| Lot | T2006002 | | | | | | | | | | | |
| Sample | 1/10 | 1/100 | 1/200 | 1/400 | 1/800 | 1/1600 | 1/3200 | 1/6400 | 1/12800 | 1/25600 | | |
| Concentration in | 8.65x | 8.65x | 4.33x | 2.16x | 1.08x | 5.41x | 2.70x | 1.35x | 6.76x | 3.38x | | |
| Dilution tested(TCID ₅₀ /mL) | 10 ⁵ | 10 ⁴ | 10 ⁴ | 10 ⁴ | 10 ⁴ | 10 ³ | 10 ³ | 10 ³ | 10 ² | 10 ² | | |
| Test Sample | 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 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.2 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.3 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.4 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.5 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Postive rate % | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 4 | 0 |
| | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 80% | 0% |

| Limit Of Detection | Virus Culture Specimen | | | | | | | | | | | |
|---|------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--------|--------|
| Lot | T2006003 | | | | | | | | | | | |
| Sample | 1/10 | 1/100 | 1/200 | 1/400 | 1/800 | 1/1600 | 1/3200 | 1/6400 | 1/12800 | 1/25600 | | |
| Concentration in | 8.65x | 8.65x | 4.33x | 2.16x | 1.08x | 5.41x | 2.70x | 1.35x | 6.76x | 3.38x | | |
| Dilution tested(TCID ₅₀ /mL) | 10 ⁵ | 10 ⁴ | 10 ⁴ | 10 ⁴ | 10 ⁴ | 10 ³ | 10 ³ | 10 ³ | 10 ² | 10 ² | | |
| Test Sample | 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 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.2 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.3 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.4 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Rep.5 | G9 | G10 | G9 | G9 | G9 | G8 | G9 | G7 | G9 | G6 | G9 | G5 |
| Postive rate % | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 4 | 0 |
| | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 80% | 0% |

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8.2 The virus culture Specimen Repeat 20 times to established LoD.

| Limit Of Detection | Virus Culture Specimen | | | | | |
|--|--------------------------|--------|--------------------------|--------|--------------------------|--------|
| Lot | T2006001 | | | | | |
| Sample | 1/3200 | | 1/6400 | | 1/12800 | |
| Concentration in Dilution tested(TCID ₅₀ /mL) | 2.70x 10 ³ | | 1.35x 10 ³ | | 6.76x 10 ² | |
| Test Sample | C line | T line | C line | T line | C line | T line |
| Rep.1 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.2 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.3 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.4 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.5 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.6 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.7 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.8 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.9 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.10 | G9 | G4 | G9 | G2 | G9 | G2 |
| Rep.11 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.12 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.13 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.14 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.15 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.16 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.17 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.18 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.19 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.20 | G9 | G4 | G9 | G3 | G9 | G3 |
| Postive rate % | 20 100% | | 19 95% | | 15 75% | |

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| Limit Of Detection | Virus Culture Specimen | | | | | |
|--|--------------------------|--------|--------------------------|--------|--------------------------|--------|
| Lot | T2006002 | | | | | |
| Sample | 1/3200 | | 1/6400 | | 1/12800 | |
| Concentration in Dilution tested(TCID ₅₀ /mL) | 2.70x 10 ³ | | 1.35x 10 ³ | | 6.76x 10 ² | |
| Test Sample | C line | T line | C line | T line | C line | T line |
| Rep.1 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.2 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.3 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.4 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.5 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.6 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.7 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.8 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.9 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.10 | G9 | G4 | G9 | G2 | G9 | G2 |
| Rep.11 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.12 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.13 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.14 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.15 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.16 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.17 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.18 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.19 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.20 | G9 | G4 | G9 | G3 | G9 | G3 |
| Postive rate % | 20 100% | | 19 95% | | 15 75% | |

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| Limit Of Detection | Virus Culture Specimen | | | | | |
|--|------------------------|--------|-----------------------|--------|-----------------------|--------|
| Lot | T2006003 | | | | | |
| Sample | 1/3200 | | 1/6400 | | 1/12800 | |
| Concentration in Dilution tested(TCID ₅₀ /mL) | 2.70x 10 ³ | | 1.35x 10 ³ | | 6.76x 10 ² | |
| Test Sample | C line | T line | C line | T line | C line | T line |
| Rep.1 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.2 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.3 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.4 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.5 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.6 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.7 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.8 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.9 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.10 | G9 | G4 | G9 | G2 | G9 | G2 |
| Rep.11 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.12 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.13 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.14 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.15 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.16 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.17 | G9 | G4 | G9 | G3 | G9 | G2 |
| Rep.18 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.19 | G9 | G4 | G9 | G3 | G9 | G3 |
| Rep.20 | G9 | G4 | G9 | G3 | G9 | G3 |
| Postive rate % | 20 | | 19 | | 15 | |
| | 100% | | 95% | | 75% | |

9. Conclusion

The results indicated that the limit of detection is the titer of 1:6400, the virus culture specimen concentration is 1.35x10³ (TCID₅₀/mL).