

**ANALYTICAL METHOD VALIDATION and REPORT**

**Hangzhou Alltest Biotech Co.,Ltd  
Rapid Diagnostics SA**

**HCV Rapid Test  
DOCUMENT NO.: RDSA0023/24 v1.2**

**ANALYTICAL METHOD VALIDATION**

**Rapid Diagnostics South Africa Pty Ltd**

**Validation  
report for**

**HCV Rapid Test  
Hangzhou Alltest Biotech Co.,Ltd**

**Document number:  
RDSA0023/24 Version 1.2**

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# ANALYTICAL METHOD VALIDATION and REPORT

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## 1 DOCUMENT APPROVAL

### Section 1: Prepared by

The signature listed below, indicate the colleague responsible for the preparation of this document.

Company	Name	Designation	Signature	Date
Rapid Diagnostics	Dr Ravesh Singh	Quality/Validation		11 June 2024

### Section 2: Reviewed and Approved by

The signature listed below, indicate the colleague responsible for the review of this document.

Company	Name	Designation	Signature	Date
Rapid Diagnostics	Prof. Veron Ramsuran	Senior Scientist		13 June 2024

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## **2 INTRODUCTION**

### **2.1 BACKGROUND**

Hepatitis C Virus (HCV) is a significant public health concern globally, causing a substantial burden of disease and mortality. In South Africa, as in many other parts of the world, HCV infection poses a considerable challenge to healthcare systems due to its high prevalence, chronic nature, and potential for severe liver complications, including cirrhosis and hepatocellular carcinoma. South Africa is home to a diverse population and faces unique challenges in the epidemiology of HCV. While precise estimates of HCV prevalence in South Africa are limited due to variations in study methodologies and population demographics, available data suggest a prevalence ranging from 0.1% to 3.2% across different regions and population groups. Certain populations are particularly vulnerable to HCV infection, including people who inject drugs (PWID), individuals living with HIV/AIDS, recipients of blood transfusions prior to the implementation of effective screening protocols, and healthcare workers exposed to contaminated blood. The clinical consequences of HCV infection in South Africa are profound, encompassing a spectrum of acute and chronic liver-related complications. Acutely, HCV infection may present as an asymptomatic or mild flu-like illness, making early detection challenging. However, without timely intervention, most of the HCV-infected individuals progress to chronic infection, placing them at increased risk of developing progressive liver fibrosis, cirrhosis, and end-stage liver disease. Importantly, the co-occurrence of HCV infection with other comorbidities, such as HIV/AIDS and non-alcoholic fatty liver disease (NAFLD), further exacerbates the risk of liver-related morbidity and mortality in affected individuals.

**RAPID DIAGNOSTICS South Africa Pty Ltd** partners with other research institutions such as Metagenomix, in collaboration with the University of KwaZulu-Natal, engaged with personnel who had the experience to materialise and implement a highly professional and trusted service. This partnership allowed the recruitment of more HCV positive individuals.

### **2.2 PURPOSE**

The HCV Rapid Test is an in-vitro diagnostic rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus in human plasma specimens. The purpose of this study is to evaluate the clinical performance of the HCV Rapid Test by Hangzhou Alltest Biotech Co., Ltd, in comparison with a state-of-the-art device with CE marking, amongst a South African population.

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## **2.3 SCOPE**

The validation study will demonstrate:

- Method suitability and performance of HCV Rapid Test from Hangzhou Alltest Biotech Co.,Ltd as a HCV antibody detection method for use on South African HCV positive patients
- The validation will compare against gold standard confirmation kit from Bio-Rad (Monalisa Anti HCV Plus Version 3)
- HCV Subtypes were determined by performing a Next generation sequencing (NGS) assay.

## **3 REFERENCE DOCUMENTS**

- HCV Rapid Test (package insert) from Hangzhou Alltest Biotech Co.,Ltd .
- Monalisa Anti HCV Plus Version 3 (Package Insert) from Bio-Rad

## **4 METHOD VALIDATION TEST PLAN**

Validation testing compares the HCV Rapid Test from Hangzhou Alltest Biotech Co.,Ltd with the Monalisa Anti HCV Plus Version 3 from Bio-Rad. A total of 178 HCV positive samples , and 222 HCV negative samples was used to assess the variability in detection of HCV and suitability of the Antibody method for the detection of HCV positive patients. The assay was performed as per manufacturer’s instructions and recommended run parameters. The NGS sequencing was performed using the MGI DNBSEQ G99 RS, and the results were validated using the online Basic Local Alignment Search Tool (BLAST) to identify specific HCV genotypes.

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## **5 VALIDATION ACCEPTANCE**

Acceptance of the method validation procedure as being complete will be dependent on the results of the various tests meeting their respective acceptance criteria. Where the acceptance criteria have not been met then a justification for acceptance of the test will be made or an action plan will be provided to correct the deficiency.

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## **6 TEST EQUIPMENT AND REFERENCE STANDARD VERIFICATION**

Complete the test equipment/instrument and reference standard list. Verify that all listed equipment/instrument is qualified and within calibration and reference standards are within expiry date. See examples below.

**Table 1: Equipment**

<b>Test Equipment</b>	<b>Instrument Reference #</b>	<b>Make</b>	<b>Status/ Verification</b>	<b>Verification expiry</b>	<b>Pass/Fail</b>
Vortex	85940	Scientific Industries Inc.	N/A	N/A	Pass
Thermal Cycler	805S9201150	Applied BioSystems	Calibrated	Sept 2023	Pass
Bio-Plex Pro Wash Station	30034376	Bio-Rad	Calibrated	Oct 2024	Pass
Multiskan FC	337-902598	Thermofisher Scientific	Calibrated	Oct 2024	Pass
General Purpose Incubator	09017910	Sheldon Manufacturing INC	Calibrated	Aug 2024	Pass
Consul21 Centrifuge	140176108	Orti Alresa	Calibrated	Jun 2024	Pass
Pipetman 1000ul	AH62703	Gilson	Calibrated	Sept 2024	Pass
Pipetman 200ul	E656986	Gilson	Calibrated	Sept 2024	Pass
200ul multichannel Pipette	QBBB356156	Axim	Calibrated	Sept 2024	Pass
DNBSEQ G99	R21007102301 17	MGI	Calibrated	Nov 2024	Pass

**Table 2: Reference Kits**

<b>Ref Std Name</b>	<b>Ref Std Batch/Lot no.#</b>	<b>Ref Std Expiry Date</b>
Monalisa Anti HCV Plus Version 3	3J0562	23 February 2025
DNBSEQ-G99RS High throughput sequencing kit	H0071	25 February 2025

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**Comments:** All consumables used were nuclease-free and within expiry. No problems experienced.  
during the validation process.

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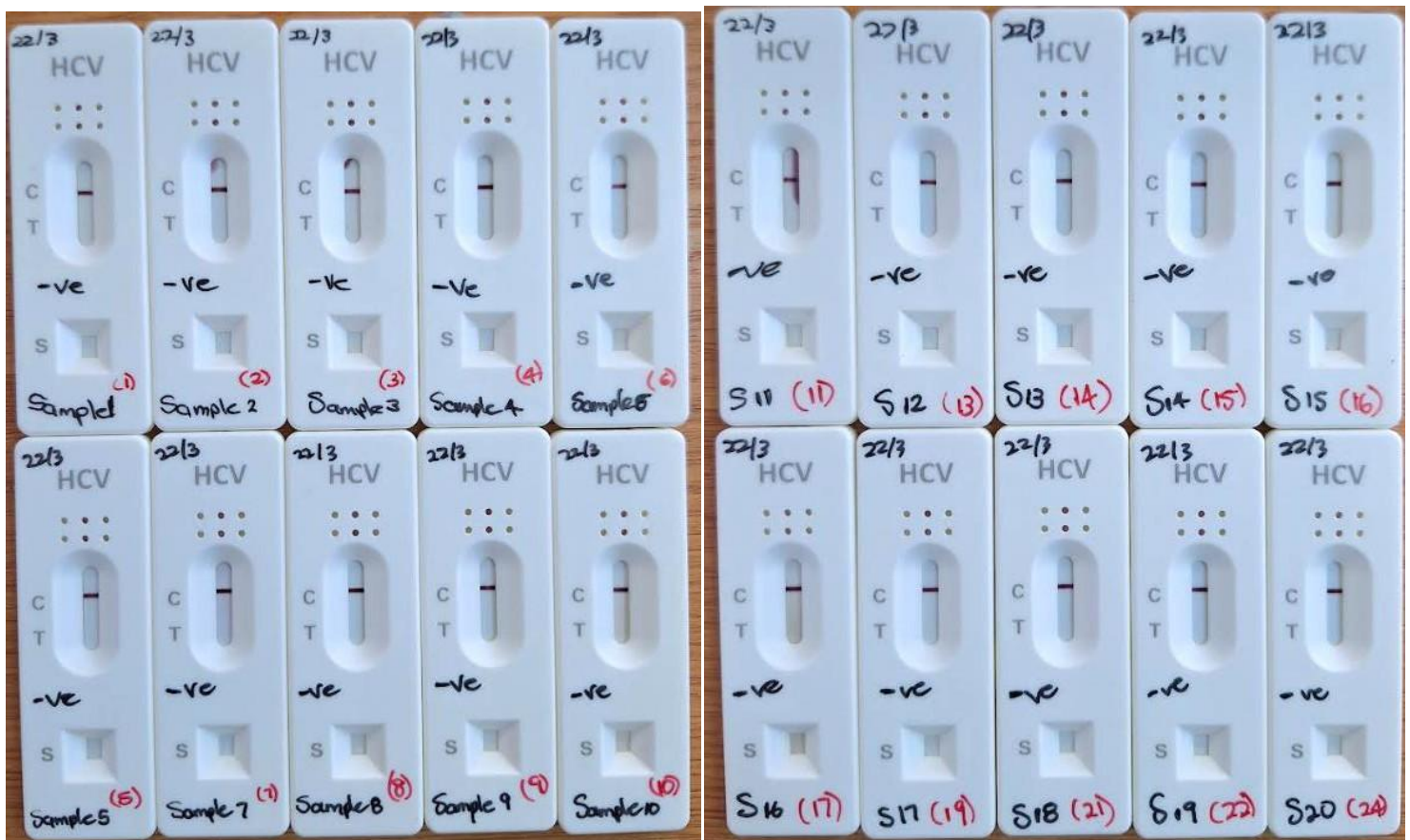
DOCUMENT NO.: RDSA0023/24 v1.2

## 7 RESULTS

### 7.1 Method Validation data

7.1.1 A total of 400 specimens were determination of the presence of HCV-specific antibodies by the Monalisa Anti HCV Plus Version 3 test. The test microplate is coated with purified recombinant antigens from the HCV virus, including NS3 and NS4 proteins and a capsid peptide. These antigens mimic the structure of the virus and are used to capture any anti- HCV antibodies present in the sample. The sample (plasma or serum) is diluted and added to the wells along with a negative and positive control. If the sample contains anti-HCV antibodies, they will bind to the corresponding antigens on the solid phase. After washing away unbound antibodies, a conjugate solution containing peroxidase -labeled anti-human IgG antibodies is added. This conjugate binds to any human IgG antibodies that have bound to the antigens. After another incubation and washing step, a substrate is added. The peroxidase enzyme catalyzes a reaction with the substrate, producing a colored product. The intensity of the color is proportional to the amount of anti-HCV antibodies present in the sample. The optical density of each well is measured using a microplate reader at 450/620- 700 nm. The absorbance value is compared to a calculated cut-off value to determine the presence or absence of anti-HCV antibodies.

7.1.2 These 400 HCV specimens were tested on the HCV Rapid Test from Hangzhou Alltest Biotech Co.,Ltd (Figures 1-20).



**Figure 1.** Twenty HCV Negative samples (S1-S20) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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**Figure 2.** Twenty HCV Negative samples (S21-S40) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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Figure 3. Twenty HCV Negative samples (S41-S60) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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**Figure 4.** Twenty HCV Negative samples (S61-S80) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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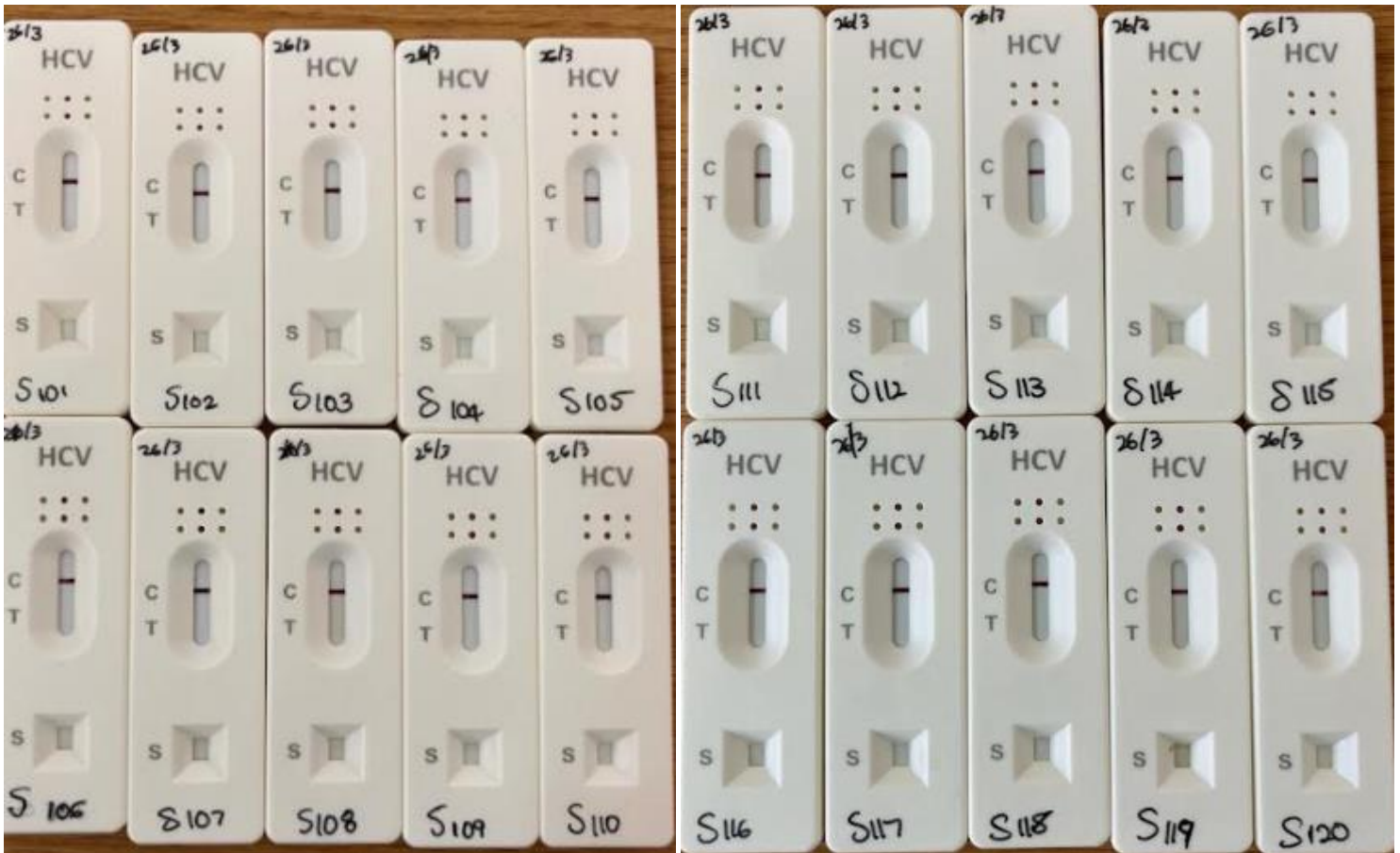
**Figure 5.** Twenty HCV Negative samples (S81-S100) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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**Figure 6.** Twenty HCV Negative samples (S101-S120) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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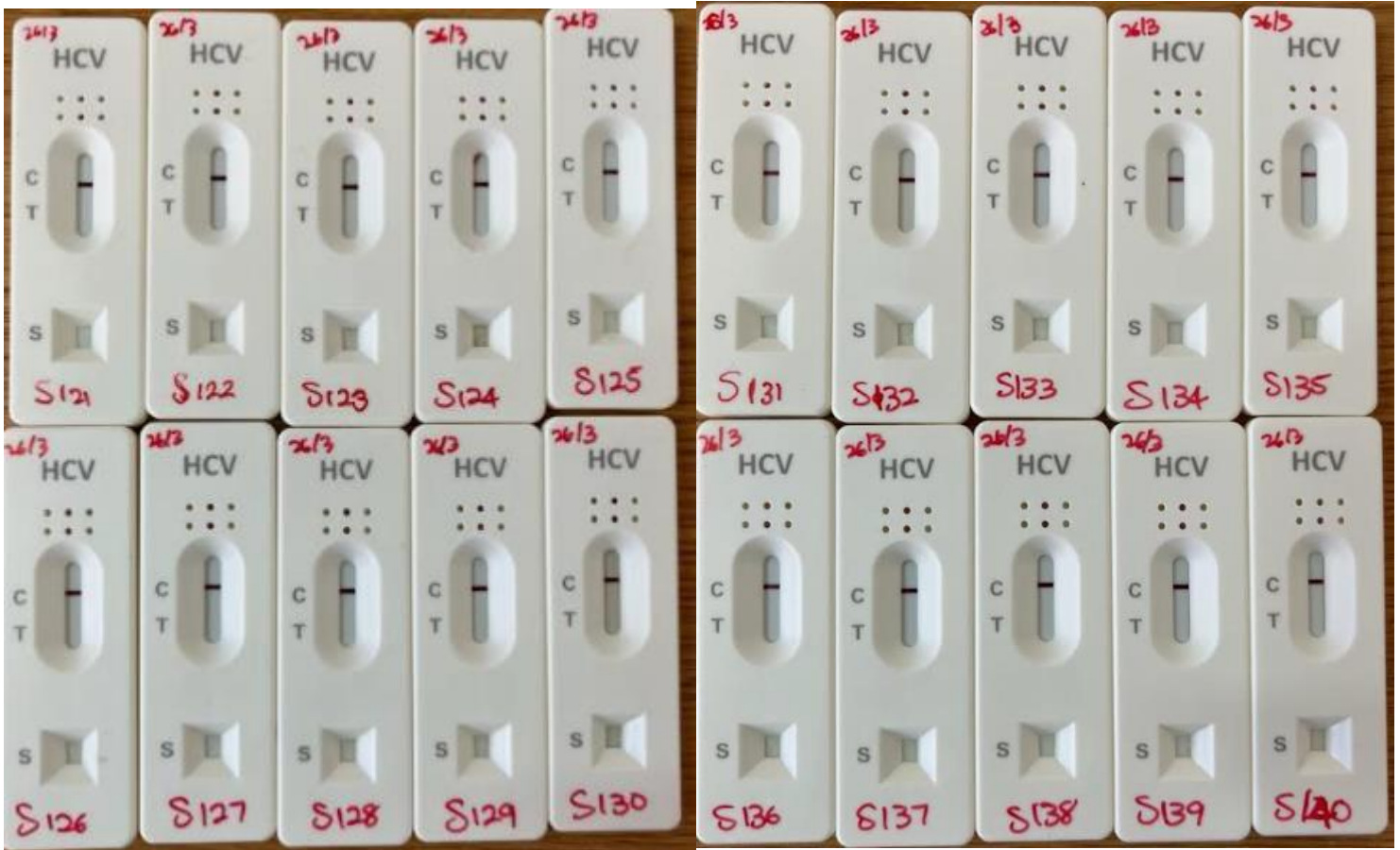


Figure 7. Twenty HCV Negative samples (S121-S140) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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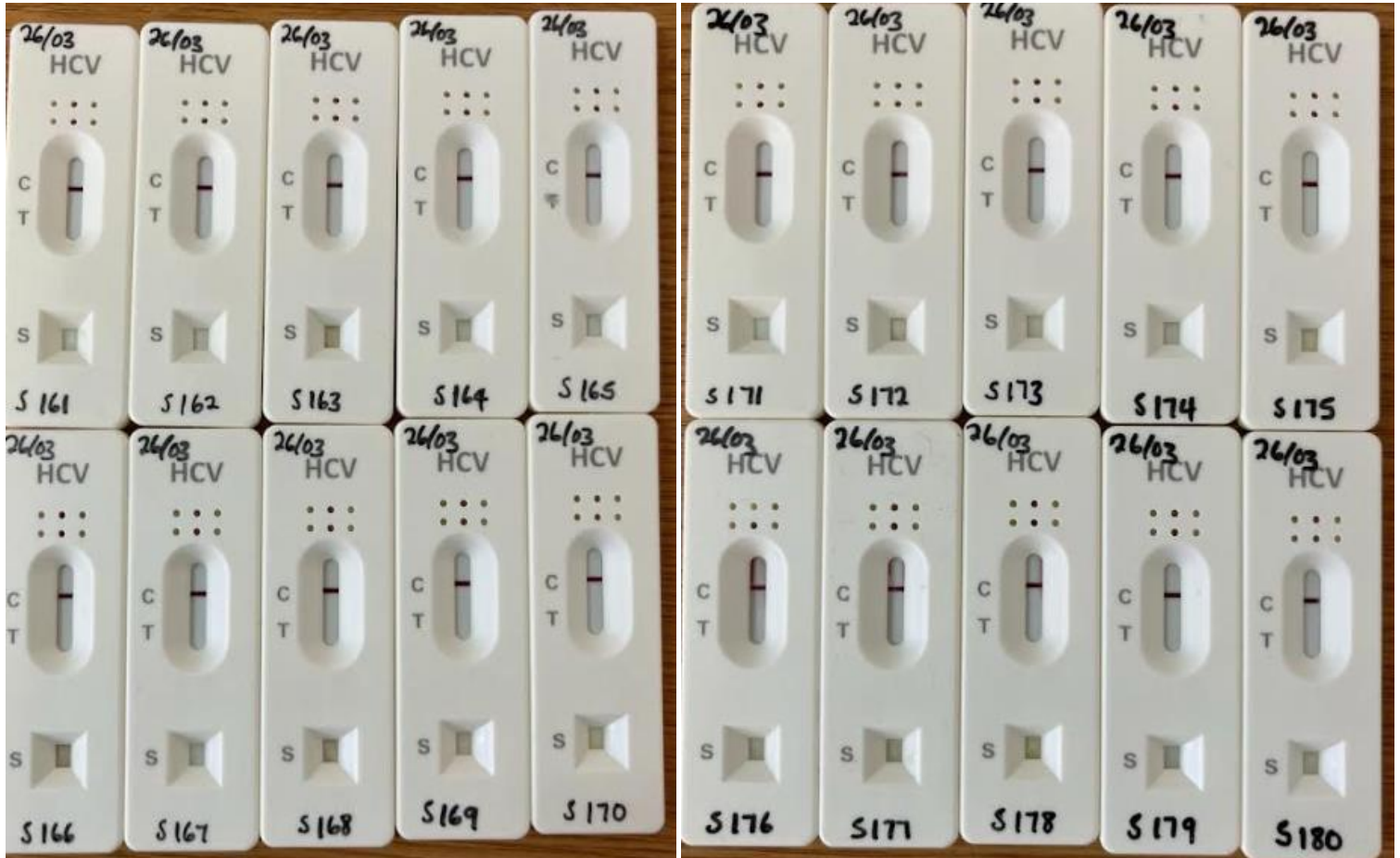
**Figure 8.** Twenty HCV Negative samples (S141-S160) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test



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**Figure 9.** Twenty HCV Negative samples (S161-S180) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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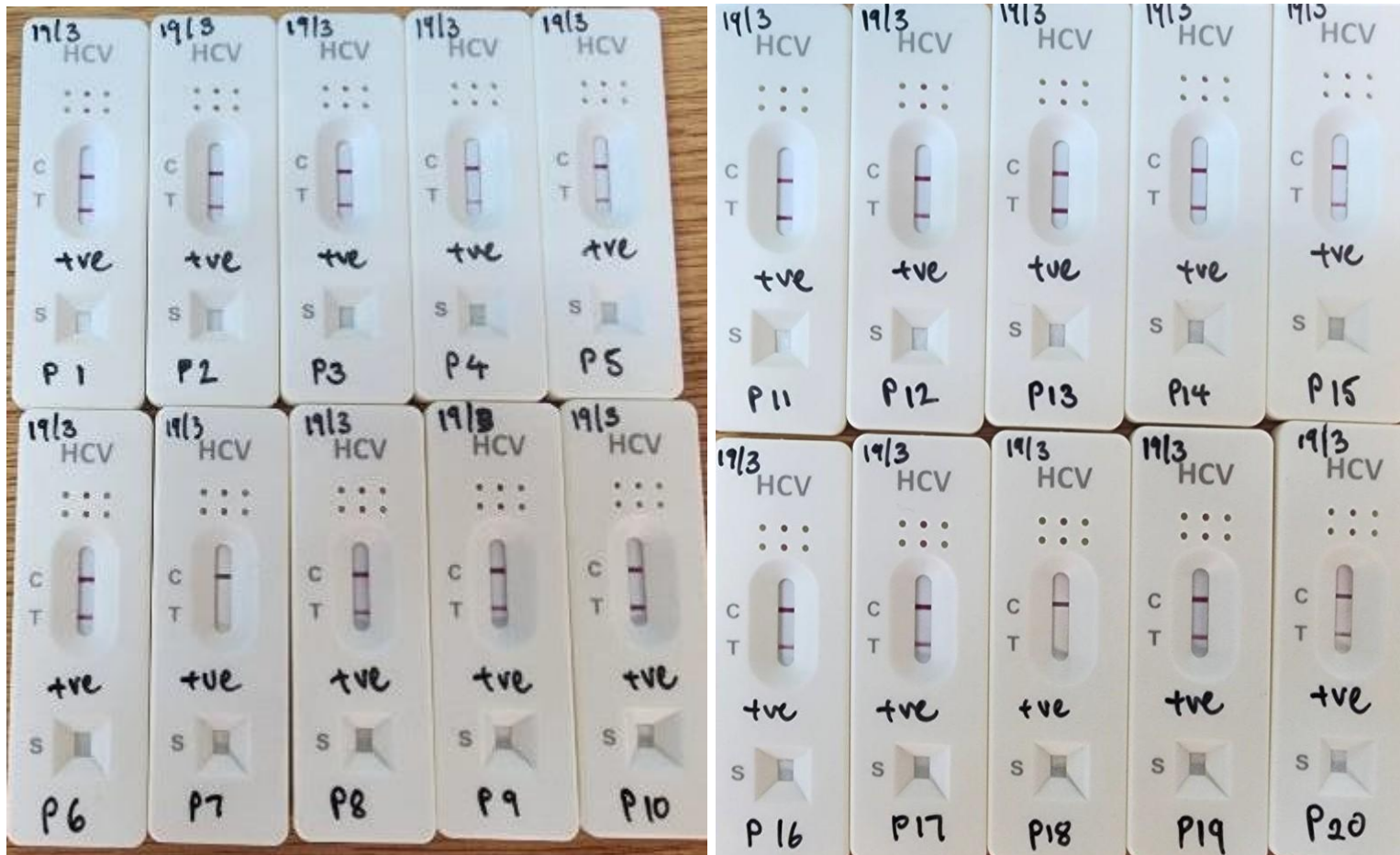
**Figure 10.** Twenty HCV Negative samples (S181-S200) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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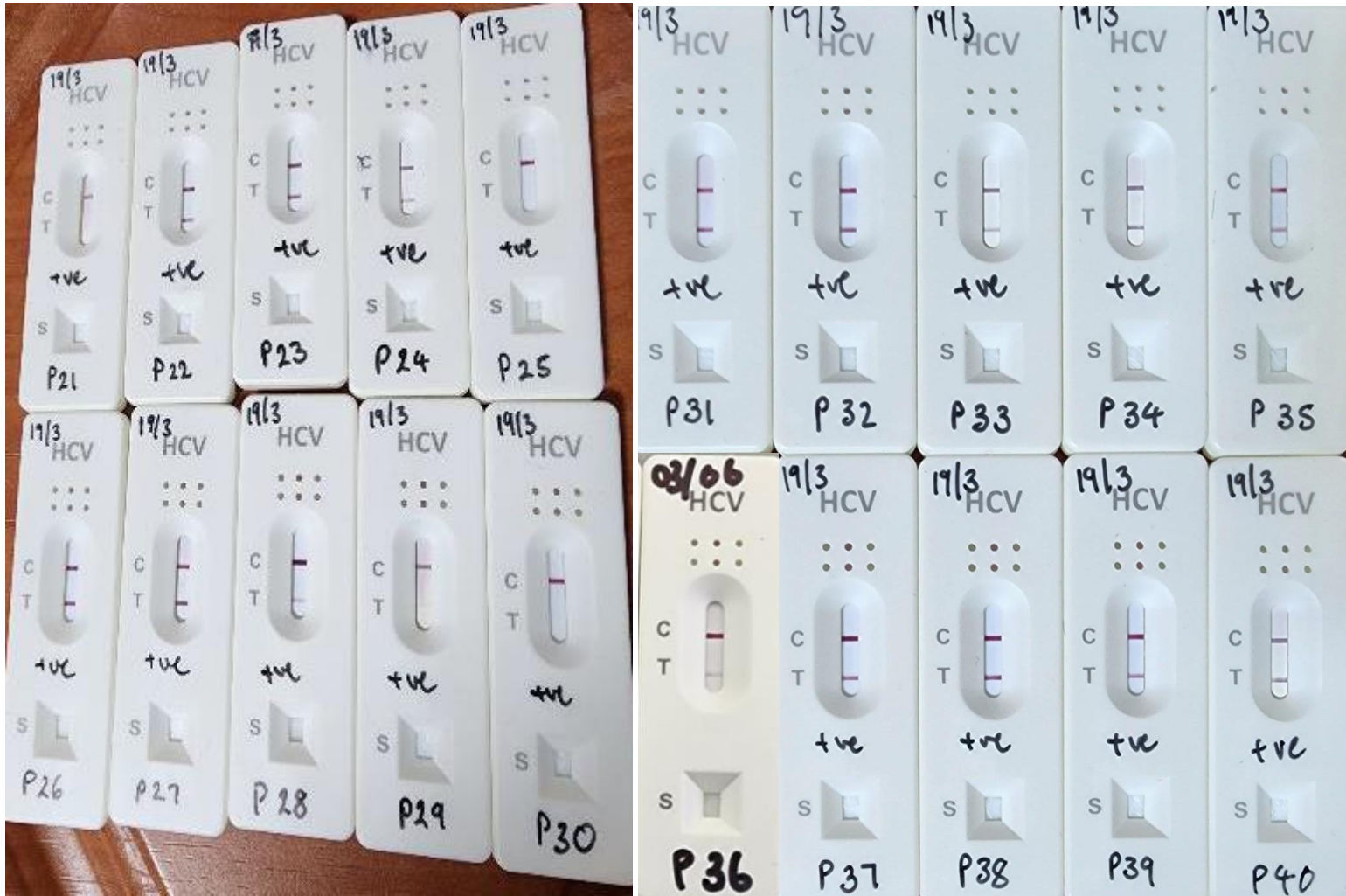
**Figure 11.** Twenty HCV samples (P1-P20) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P7 and P18 were negative.

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**Figure 12.** Twenty HCV samples (P21-P40) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P21, P25, P29 and P30 were negative.

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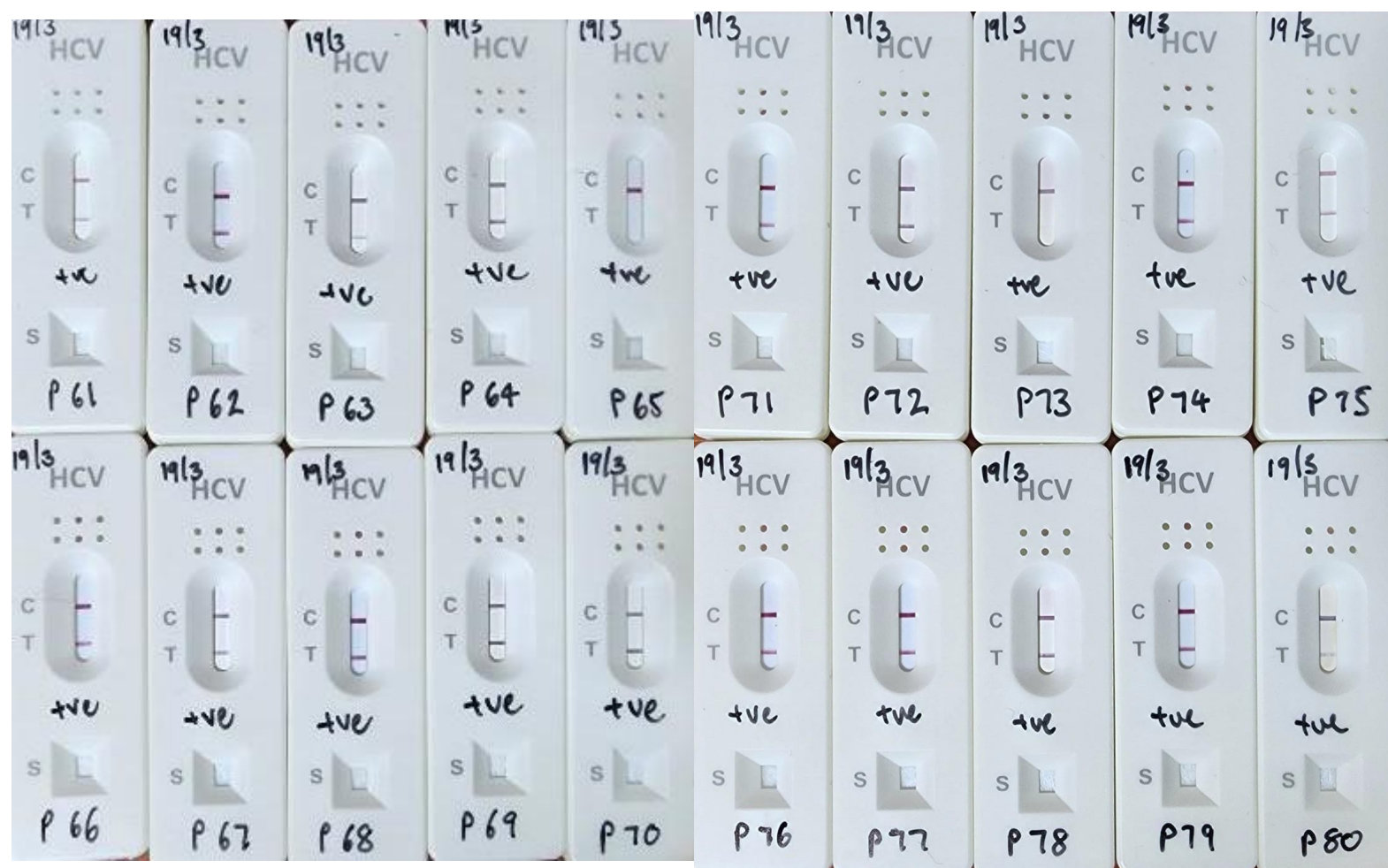
**Figure 13.** Twenty HCV samples (P41-P60) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P43 and P49 were negative.

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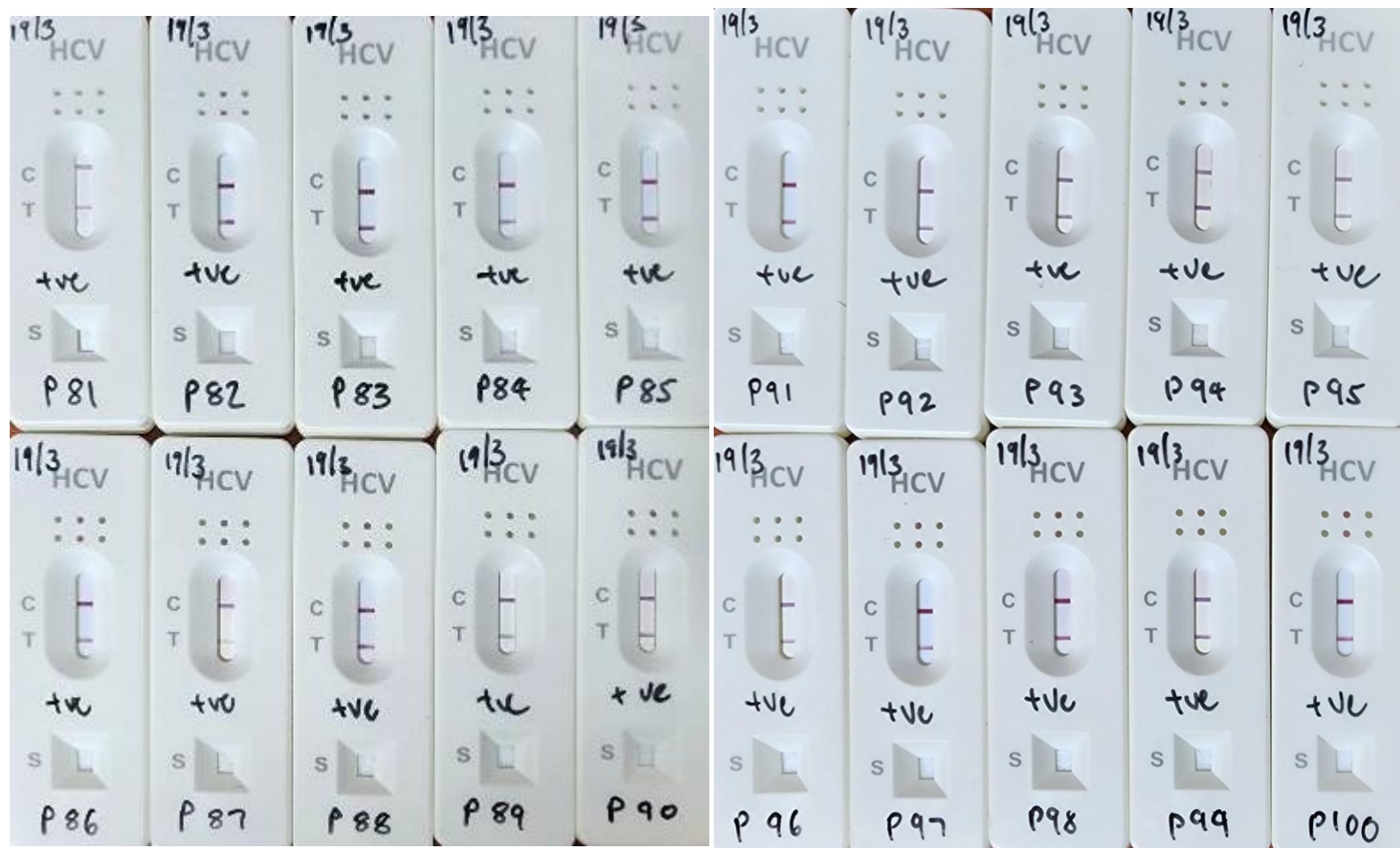
**Figure 14.** Twenty HCV samples (P61-P80) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P65 and P73 were negative.

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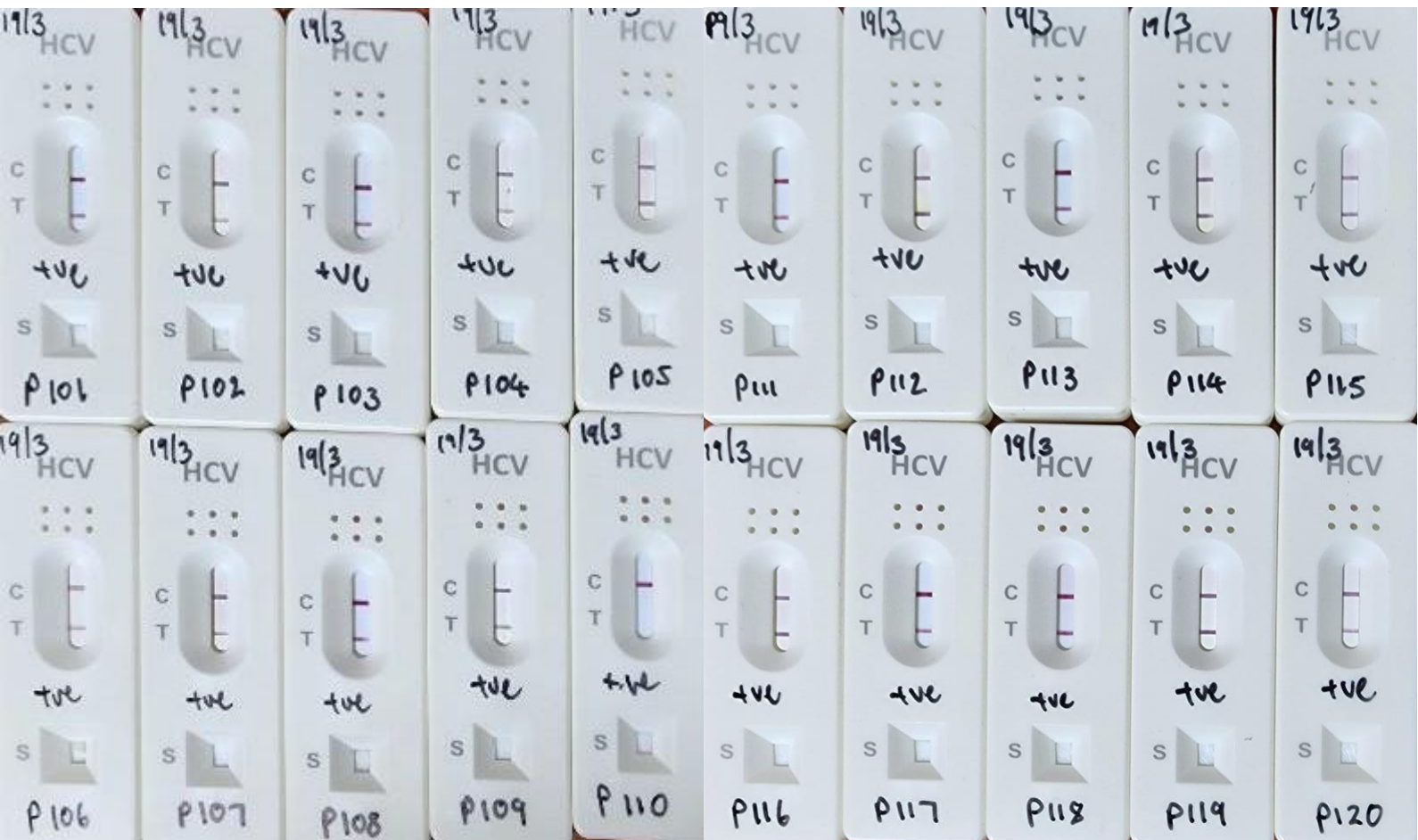
**Figure 15.** Twenty HCV Positive samples (P81-P100) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test

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**Figure 16.** Twenty HCV samples (P101-P120) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Sample labelled P110 were negative.

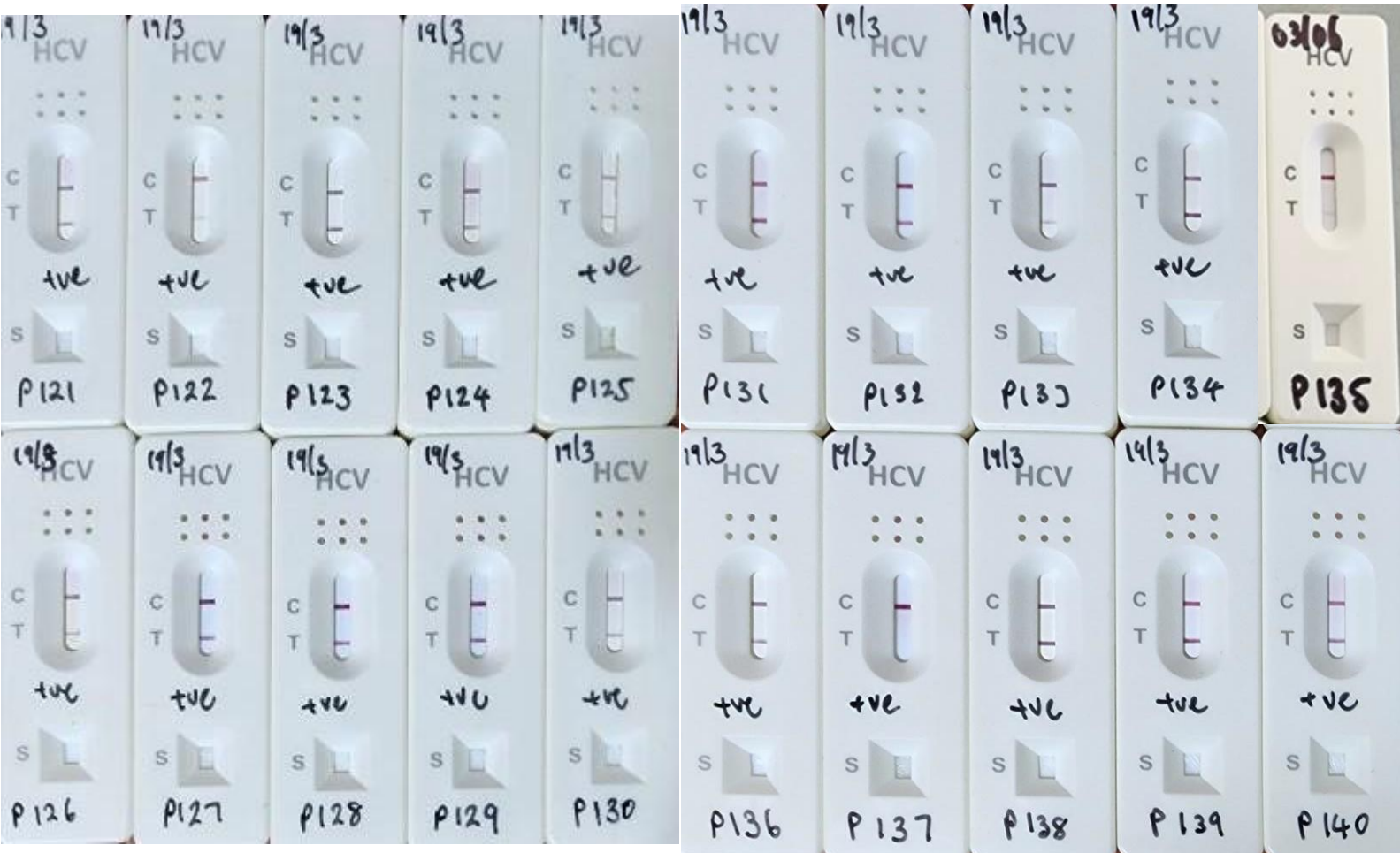


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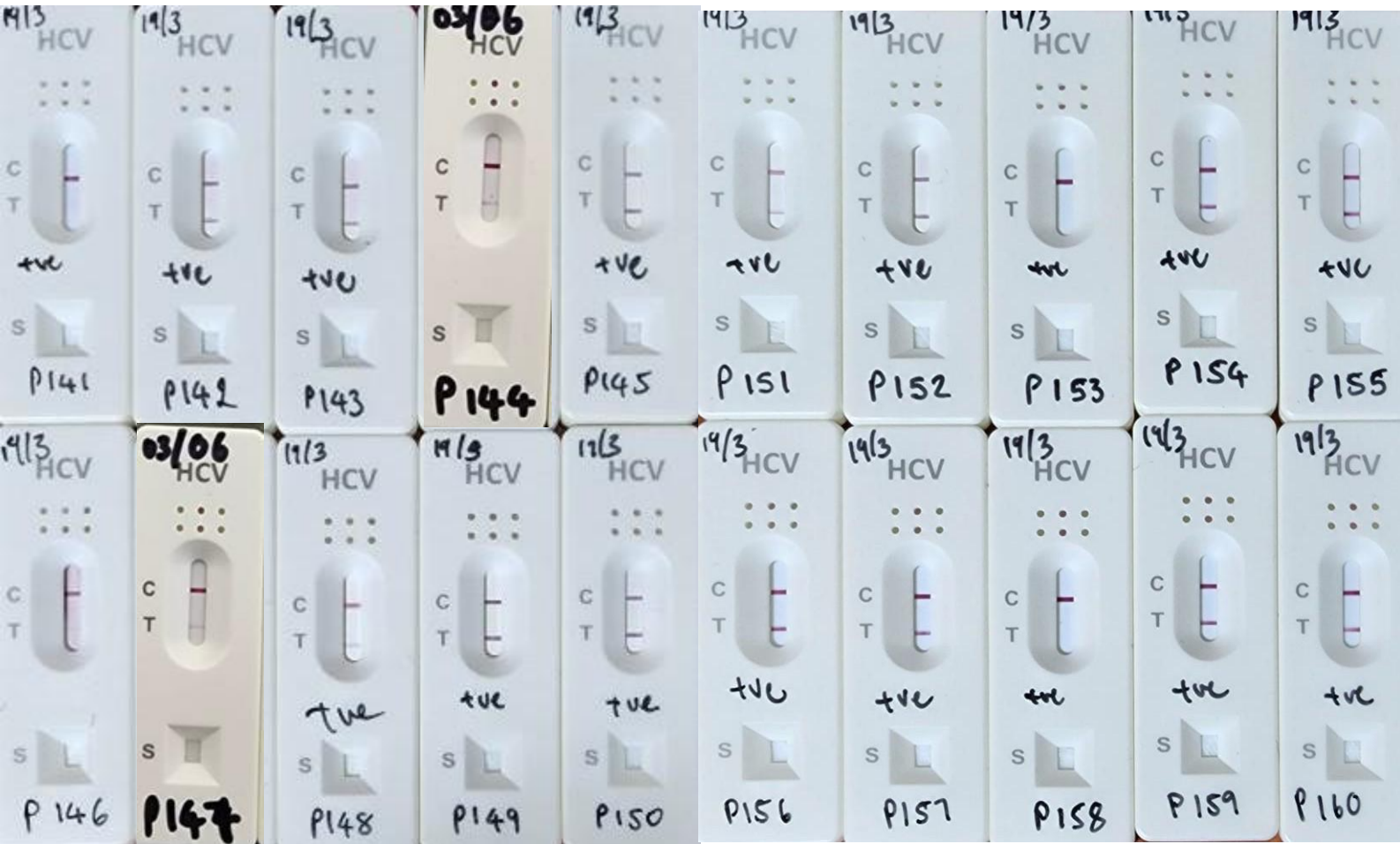
**Figure 17.** Twenty HCV samples (P121-P140) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P137 were negative.

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**Figure 18.** Twenty HCV samples (P141-P160) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P141, P146, P153 and P158 were negative.



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**Figure 20.** Twenty HCV samples (P181-P200) run on the Hangzhou Alltest Biotech Co.,Ltd HCV Rapid Test. Samples labelled P192, P197 and P198 were negative.

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## 7.2 Comparative data

HCV antibody presence is detected using Bio-Rad Monalisa Anti HCV Plus Version 3 kit and the HCV Rapid test from Hangzhou Alltest Biotech Co.,Ltd. HCV subtypes are determined using NGS sequencing for 30 randomly selected samples. The ELISA results measured using the Bio-Rad Monalisa Anti HCV Plus Version 3 kit generates a raw data result, which needs to be analysed using a guideline specified with the protocol. The analysis was performed as follows; Calculate the mean measured absorbance value for the positive control.

Calculation of the cut off value (CO):  $CO = \text{Mean OD (positive control)} \times 0.4$

The presence or absence of anti-HCV antibodies is determined by comparing the registered absorbency to the calculated cut-off value for each sample. The following ratio is calculated for each sample:

Ratio = OD of the sample / CO Value

Samples with an optical density lower than the cut off value are considered to be negative (ratio < 1) by the Monalisa™ Anti-HCV PLUS Version 3.

In this report, samples with cut-off values just below ( $CO - 10\% < O.D. < CO$ , ratio between 0.9 and 1) was interpreted with caution as highlighted in the Monalisa™ Anti-HCV PLUS Version 3 IFU. Raw data and Analysed data for the Bio-Rad Monalisa Anti HCV Plus Version 3 kit are shown for each sample tested in the Table 3.

NGS sequencing was performed using the MGI DNBSEQ G99 RS. The results were validated using the online Basic Local Alignment Search Tool (BLAST) and specific HCV Subtypes were identified. Each Subtype is shown in Table 3 for the 30 samples sequenced.

**Table 3: Comparative data Table.** HCV antibody presence is detected using Bio-Rad Monalisa Anti HCV Plus Version 3 kit and the HCV Rapid test from Hangzhou Alltest Biotech Co.,Ltd.

No	Specimen No	Type of Specimen	Sample collection date	Result					HCV Genotype
				Candidate Device Rapid Test		Reference test ELISA			
				Test result	Test Date	Analyzed Data	Test Result	Test Date	
P1	DR-00602	Plasma	15-06-2023	Positive	19/03/2024	1.5560439 56	Weakly Positive	11/03/2024	N/A
P2	DR-00734	Plasma	15-06-2023	Positive	19/03/2024	1.0681318 68	Weakly Positive	11/03/2024	N/A
P3	DR-00792	Plasma	19-06-2023	Positive	19/03/2024	3.0461538 46	Positive	11/03/2024	Type 5
P4	DR-00865	Plasma	20-06-2023	Positive	19/03/2024	2.5582417 58	Positive	11/03/2024	N/A
P5	DR-00891	Plasma	20-06-2023	Positive	19/03/2024	1.3450549 45	Weakly Positive	11/03/2024	N/A
P7	DR-01047	Plasma	20-06-2023	Negative	19/03/2024	0.9098901 1	Negative	11/03/2024	N/A
P6	DR-01177	Plasma	25-04-2023	Positive	19/03/2024	1.3186813 19	Weakly Positive	11/03/2024	N/A
P11	DR-01297	Plasma	21-09-2023	Positive	19/03/2024	1.2395604 4	Weakly Positive	11/03/2024	N/A

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P8	DR-01857	Plasma	21-06-2023	Positive	19/03/2024	1.1604395 6	Weakly Positive	11/03/202 4	N/A
P9	DR-01858	Plasma	14-06-2023	Positive	19/03/2024	2.6769230 77	Positive	11/03/202 4	N/A
P10	DR-01904	Plasma	21-06-2023	Positive	19/03/2024	1.2791208 79	Weakly Positive	11/03/202 4	N/A
P14	DR-01994	Plasma	23-06-2023	Positive	19/03/2024	1.0945054 95	Weakly Positive	11/03/202 4	N/A
P12	DR-02144	Plasma	22-06-2023	Positive	19/03/2024	1.0417582 42	Weakly Positive	11/03/202 4	Type 5
P13	DR-02238	Plasma	22-06-2023	Positive	19/03/2024	1.3054945 05	Weakly Positive	11/03/202 4	N/A
P18	DR-02370	Plasma	09-01-2024	Negative	19/03/2024	0.9098901 1	Negative	11/03/202 4	N/A
P17	DR-02371	Plasma	27-06-2023	Positive	19/03/2024	1.0549450 55	Weakly Positive	11/03/202 4	N/A
P16	DR-02387	Plasma	26-06-2023	Positive	19/03/2024	1.9252747 25	Weakly Positive	11/03/202 4	N/A
P15	DR-02398	Plasma	26-10-2023	Positive	19/03/2024	3.0329670 33	Positive	11/03/202 4	N/A
P19	DR-02411	Plasma	10-01-2024	Positive	19/03/2024	1.1604395 6	Weakly Positive	11/03/202 4	N/A
P20	DR-02494	Plasma	18-01-2024	Positive	19/03/2024	1.4505494 51	Weakly Positive	11/03/202 4	N/A
P21	DR-02557	Plasma	19-01-2024	Negative	19/03/2024	0.8703296 7	Negative	11/03/202 4	N/A
P22	DR-02586	Plasma	19-01-2024	Positive	19/03/2024	1.3054945 05	Weakly Positive	11/03/202 4	Type 6
P27	DR-02690	Plasma	06-01-2024	Positive	19/03/2024	1.0153846 15	Weakly Positive	11/03/202 4	N/A
S1	DR-02700	Plasma	06-09-2023	Negative	22/03/2024	0.5064377 68	Negative	12/03/202 4	N/A
S4	DR-02711	Plasma	07-09-2023	Negative	22/03/2024	0.4163090 13	Negative	12/03/202 4	N/A
S6	DR-02715	Plasma	07-09-2023	Negative	22/03/2024	0.2145922 75	Negative	12/03/202 4	N/A
S8	DR-02716	Plasma	06-12-2023	Negative	22/03/2024	0.1888412 02	Negative	12/03/202 4	N/A
S9	DR-02733	Plasma	07-09-2023	Negative	22/03/2024	0.4356223 18	Negative	12/03/202 4	N/A
S11	DR-02737	Plasma	15-10-2023	Negative	22/03/2024	0.2017167 38	Negative	12/03/202 4	N/A
S13	DR-02740	Plasma	28-11-2023	Negative	22/03/2024	0.2124463 52	Negative	12/03/202 4	N/A
S14	DR-02744	Plasma	07-09-2023	Negative	22/03/2024	0.1781115 88	Negative	12/03/202 4	N/A
S15	DR-02748	Plasma	07-09-2023	Negative	22/03/2024	0.4935622 32	Negative	12/03/202 4	N/A
P28	DR-02749	Plasma	28-01-2024	Positive	03/06/2024	1.0585970 92	Positive	30/05/202 4	N/A
S16	DR-02755	Plasma	07-09-2023	Negative	22/03/2024	0.3133047 21	Negative	12/03/202 4	N/A

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P29	DR-02761	Plasma	06-01-2024	Negative	19/03/2024	0.7516483 52	Negative	11/03/202 4	N/A
S12	DR-02815	Plasma	07-11-2023	Negative	22/03/2024	0.1695278 97	Negative	12/03/202 4	N/A
S10	DR-02833	Plasma	07-09-2023	Negative	22/03/2024	0.2081545 06	Negative	12/03/202 4	N/A
S7	DR-02845	Plasma	07-09-2023	Negative	22/03/2024	0.1480686 7	Negative	12/03/202 4	N/A
S5	DR-02849	Plasma	24-03-2023	Negative	22/03/2024	0.2188841 2	Negative	12/03/202 4	N/A
S3	DR-02850	Plasma	06-09-2023	Negative	22/03/2024	0.4957081 55	Negative	12/03/202 4	N/A
S2	DR-02851	Plasma	06-09-2023	Negative	22/03/2024	0.1738197 42	Negative	12/03/202 4	N/A
P26	DR-02876	Plasma	12-01-2024	Positive	19/03/2024	1.3450549 45	Weakly Positive	11/03/202 4	N/A
P25	DR-02878	Plasma	10-01-2024	Negative	19/03/2024	0.8703296 7	Negative	11/03/202 4	N/A
P23	DR-02893	Plasma	09-01-2024	Positive	19/03/2024	1.1868131 87	Weakly Positive	11/03/202 4	N/A
P24	DR-02899	Plasma	10-01-2024	Positive	19/03/2024	1.1208791 21	Weakly Positive	11/03/202 4	N/A
P30	DR-02907	Plasma	08-01-2024	Negative	19/03/2024	0.8307692 31	Negative	11/03/202 4	N/A
S17	DR-02913	Plasma	29-11-2023	Negative	22/03/2024	0.1716738 2	Negative	12/03/202 4	N/A
S18	DR-02914	Plasma	07-01-2024	Negative	22/03/2024	0.1480686 7	Negative	12/03/202 4	N/A
S19	DR-02929	Plasma	15-01-2024	Negative	22/03/2024	0.1888412 02	Negative	12/03/202 4	N/A
S35	DR-02982	Plasma	13-01-2024	Negative	22/03/2024	0.2124463 52	Negative	12/03/202 4	N/A
S20	DR-02983	Plasma	07-09-2023	Negative	22/03/2024	0.2360515 02	Negative	12/03/202 4	N/A
S23	DR-02986	Plasma	07-09-2023	Negative	22/03/2024	0.1931330 47	Negative	12/03/202 4	N/A
S25	DR-03001	Plasma	08-09-2023	Negative	22/03/2024	0.1416309 01	Negative	12/03/202 4	N/A
S28	DR-03012	Plasma	09-09-2023	Negative	22/03/2024	0.1502145 92	Negative	12/03/202 4	N/A
S30	DR-03015	Plasma	08-01-2024	Negative	22/03/2024	0.1351931 33	Negative	12/03/202 4	N/A
S31	DR-03023	Plasma	09-01-2024	Negative	22/03/2024	0.1630901 29	Negative	12/03/202 4	N/A
S33	DR-03026	Plasma	10-04-2023	Negative	22/03/2024	0.2381974 25	Negative	12/03/202 4	N/A
S37	DR-03036	Plasma	12-04-2023	Negative	22/03/2024	0.2489270 39	Negative	12/03/202 4	N/A
S36	DR-03049	Plasma	09-09-2023	Negative	22/03/2024	0.1587982 83	Negative	12/03/202 4	N/A
S38	DR-03069	Plasma	09-09-2023	Negative	22/03/2024	0.3648068 67	Negative	12/03/202 4	N/A

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S39	DR-03077	Plasma	10-09-2023	Negative	22/03/2024	0.2639484 98	Negative	12/03/202 4	N/A
S32	DR-03112	Plasma	09-09-2023	Negative	22/03/2024	0.1952789 7	Negative	12/03/202 4	N/A
S41	DR-03123	Plasma	14-07-2023	Negative	22/03/2024	0.1759656 65	Negative	12/03/202 4	N/A
S34	DR-03125	Plasma	09-09-2023	Negative	22/03/2024	0.2403433 48	Negative	12/03/202 4	N/A
S40	DR-03128	Plasma	23-05-2023	Negative	22/03/2024	0.2167381 97	Negative	12/03/202 4	N/A
S29	DR-03147	Plasma	06-01-2024	Negative	22/03/2024	0.1223175 97	Negative	12/03/202 4	N/A
S27	DR-03151	Plasma	09-09-2023	Negative	22/03/2024	0.1652360 52	Negative	12/03/202 4	N/A
S26	DR-03154	Plasma	08-09-2023	Negative	22/03/2024	0.2188841 2	Negative	12/03/202 4	N/A
S24	DR-03168	Plasma	07-09-2023	Negative	22/03/2024	0.1824034 33	Negative	12/03/202 4	N/A
S22	DR-03173	Plasma	07-09-2023	Negative	22/03/2024	0.2124463 52	Negative	12/03/202 4	N/A
S21	DR-03178	Plasma	07-09-2023	Negative	22/03/2024	0.1416309 01	Negative	12/03/202 4	N/A
S42	DR-03790	Plasma	10-09-2023	Negative	22/03/2024	0.2124463 52	Negative	12/03/202 4	N/A
S43	DR-03802	Plasma	10-09-2023	Negative	22/03/2024	0.1459227 47	Negative	12/03/202 4	N/A
S44	DR-03804	Plasma	10-09-2023	Negative	22/03/2024	0.3841201 72	Negative	12/03/202 4	N/A
S45	DR-03851	Plasma	10-08-2023	Negative	22/03/2024	0.2618025 75	Negative	12/03/202 4	N/A
P32	DR-03854	Plasma	09-01-2024	Positive	19/03/2024	1.2000000 00	Weakly Positive	11/03/202 4	N/A
P31	DR-03855	Plasma	09-01-2024	Positive	19/03/2024	1.0021978 02	Weakly Positive	11/03/202 4	N/A
P33	DR-03856	Plasma	09-01-2024	Positive	19/03/2024	1.4637362 64	Weakly Positive	11/03/202 4	N/A
S46	DR-03858	Plasma	11-08-2023	Negative	22/03/2024	0.2038626 61	Negative	12/03/202 4	N/A
P34	DR-03864	Plasma	22-01-2024	Positive	19/03/2024	1.4769230 77	Weakly Positive	11/03/202 4	N/A
S47	DR-03878	Plasma	10-09-2023	Negative	22/03/2024	0.1759656 65	Negative	12/03/202 4	N/A
S48	DR-03906	Plasma	23-09-2023	Negative	22/03/2024	0.1673819 74	Negative	12/03/202 4	N/A
P35	DR-03910	Plasma	11-01-2024	Positive	19/03/2024	1.3054945 05	Weakly Positive	11/03/202 4	N/A
S49	DR-03913	Plasma	13-09-2023	Negative	22/03/2024	0.1437768 24	Negative	12/03/202 4	N/A
S50	DR-03932	Plasma	13-09-2023	Negative	22/03/2024	0.1845493 56	Negative	12/03/202 4	N/A
P36	DR-03939	Plasma	11-01-2024	Positive	03/06/2024	1.0094097 52	Positive	30/05/202 4	N/A



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S51	DR-03974	Plasma	21-09-2023	Negative	22/03/2024	0.1695278 97	Negative	12/03/202 4	N/A
P37	DR-03982	Plasma	12-01-2024	Positive	19/03/2024	1.5296703 3	Weakly Positive	11/03/202 4	N/A
P38	DR-03983	Plasma	13-01-2024	Positive	19/03/2024	2.2417582 42	Positive	11/03/202 4	Type 4
S52	DR-04004	Plasma	13-09-2023	Negative	22/03/2024	0.1974248 93	Negative	12/03/202 4	N/A
S53	DR-04036	Plasma	13-09-2023	Negative	22/03/2024	0.1802575 11	Negative	12/03/202 4	N/A
S80	DR-04057	Plasma	16-09-2023	Negative	22/03/2024	0.2081545 06	Negative	12/03/202 4	N/A
S81	DR-04066	Plasma	16-09-2023	Negative	22/03/2024	0.3261802 58	Negative	12/03/202 4	N/A
S54	DR-04083	Plasma	13-09-2023	Negative	22/03/2024	0.6330472 1	Negative	12/03/202 4	N/A
S55	DR-04085	Plasma	11-05-2023	Negative	22/03/2024	0.2253218 88	Negative	12/03/202 4	N/A
S56	DR-04089	Plasma	13-09-2023	Negative	22/03/2024	0.2682403 43	Negative	12/03/202 4	N/A
S63	DR-04096	Plasma	14-09-2023	Negative	22/03/2024	0.1802575 11	Negative	12/03/202 4	N/A
S74	DR-04106	Plasma	14-09-2023	Negative	22/03/2024	0.1888412 02	Negative	12/03/202 4	N/A
S62	DR-04116	Plasma	14-09-2023	Negative	22/03/2024	0.2060085 84	Negative	12/03/202 4	N/A
S69	DR-04134	Plasma	14-09-2023	Negative	22/03/2024	0.6394849 79	Negative	12/03/202 4	N/A
S71	DR-04148	Plasma	13-09-2023	Negative	22/03/2024	0.2296137 34	Negative	12/03/202 4	N/A
S60	DR-04154	Plasma	13-09-2023	Negative	22/03/2024	0.2510729 61	Negative	12/03/202 4	N/A
S89	DR-04155	Plasma	07-09-2023	Negative	22/03/2024	0.1824034 33	Negative	12/03/202 4	N/A
S72	DR-04157	Plasma	14-09-2023	Negative	22/03/2024	0.2038626 61	Negative	12/03/202 4	N/A
S83	DR-04164	Plasma	16-09-2023	Negative	22/03/2024	0.2081545 06	Negative	12/03/202 4	N/A
S61	DR-04195	Plasma	14-09-2023	Negative	22/03/2024	0.1866952 79	Negative	12/03/202 4	N/A
S75	DR-04196	Plasma	14-07-2023	Negative	22/03/2024	0.1909871 24	Negative	12/03/202 4	N/A
S57	DR-04200	Plasma	16-05-2023	Negative	22/03/2024	0.1523605 15	Negative	12/03/202 4	N/A
S58	DR-04207	Plasma	13-09-2023	Negative	22/03/2024	0.2403433 48	Negative	12/03/202 4	N/A
S64	DR-04210	Plasma	21-09-2023	Negative	22/03/2024	0.2145922 75	Negative	12/03/202 4	N/A
S79	DR-04225	Plasma	22-10-2023	Negative	22/03/2024	0.2339055 79	Negative	12/03/202 4	N/A
S65	DR-04237	Plasma	14-09-2023	Negative	22/03/2024	0.1416309 01	Negative	12/03/202 4	N/A

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S78	DR-04242	Plasma	15-09-2023	Negative	22/03/2024	0.1824034 33	Negative	12/03/2024 4	N/A
S66	DR-04245	Plasma	26-05-2023	Negative	22/03/2024	0.1909871 24	Negative	12/03/2024 4	N/A
S59	DR-04248	Plasma	14-09-2023	Negative	22/03/2024	0.2188841 2	Negative	12/03/2024 4	N/A
S67	DR-04255	Plasma	14-09-2023	Negative	22/03/2024	0.2553648 07	Negative	12/03/2024 4	N/A
S68	DR-04257	Plasma	14-09-2023	Negative	22/03/2024	0.3540772 53	Negative	12/03/2024 4	N/A
S87	DR-04282	Plasma	15-11-2023	Negative	22/03/2024	0.1952789 7	Negative	12/03/2024 4	N/A
S73	DR-04295	Plasma	16-09-2023	Negative	22/03/2024	0.1330472 1	Negative	12/03/2024 4	N/A
S76	DR-04310	Plasma	14-09-2023	Negative	22/03/2024	0.1952789 7	Negative	12/03/2024 4	N/A
S70	DR-04323	Plasma	28-06-2023	Negative	22/03/2024	0.2296137 34	Negative	12/03/2024 4	N/A
S85	DR-04337	Plasma	12-08-2023	Negative	22/03/2024	0.1931330 47	Negative	12/03/2024 4	N/A
S93	DR-04354	Plasma	16-09-2023	Negative	22/03/2024	0.3052232 18	Negative	18/03/2024 4	N/A
S92	DR-04372	Plasma	16-09-2023	Negative	22/03/2024	0.3235825 1	Negative	18/03/2024 4	N/A
S94	DR-04431	Plasma	16-09-2023	Negative	22/03/2024	0.2547351 67	Negative	18/03/2024 4	N/A
P42	DR-04460	Plasma	05-10-2023	Positive	19/03/2024	1.3054945 05	Weakly Positive	11/03/2024 4	N/A
P40	DR-04470	Plasma	23-06-2023	Positive	19/03/2024	1.3318681 32	Weakly Positive	11/03/2024 4	N/A
S88	DR-04479	Plasma	16-09-2023	Negative	22/03/2024	0.3798283 26	Negative	12/03/2024 4	N/A
P41	DR-04484	Plasma	09-01-2024	Positive	19/03/2024	1.0813186 81	Weakly Positive	11/03/2024 4	N/A
S90	DR-04521	Plasma	09-09-2023	Negative	22/03/2024	0.1716738 2	Negative	12/03/2024 4	N/A
S91	DR-04523	Plasma	09-09-2023	Negative	22/03/2024	0.1738197 42	Negative	12/03/2024 4	N/A
S84	DR-04524	Plasma	23-07-2023	Negative	22/03/2024	0.2188841 2	Negative	12/03/2024 4	N/A
S86	DR-04531	Plasma	15-08-2023	Negative	22/03/2024	0.2038626 61	Negative	12/03/2024 4	N/A
P39	DR-04540	Plasma	08-01-2024	Positive	19/03/2024	1.6219780 22	Weakly Positive	11/03/2024 4	N/A
S97	DR-04628	Plasma	16-09-2023	Negative	22/03/2024	0.4934059 55	Negative	18/03/2024 4	N/A
S99	DR-04629	Plasma	14-01-2024	Negative	22/03/2024	0.3350570 67	Negative	18/03/2024 4	N/A
S101	DR-04636	Plasma	16-01-2024	Negative	22/03/2024	0.2363758 76	Negative	18/03/2024 4	N/A
S104	DR-04661	Plasma	08-01-2024	Negative	22/03/2024	0.4612771 95	Negative	18/03/2024 4	N/A

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S106	DR-04679	Plasma	08-01-2024	Negative	22/03/2024	0.4268535 23	Negative	18/03/202 4	N/A
P43	DR-04680	Plasma	23-07-2023	Negative	19/03/2024	0.8967032 97	Negative	11/03/202 4	N/A
S108	DR-04682	Plasma	21-01-2024	Negative	22/03/2024	0.5232398 03	Negative	18/03/202 4	N/A
P45	DR-04686	Plasma	11-06-2023	Positive	19/03/2024	1.6087912 09	Weakly Positive	11/03/202 4	N/A
S109	DR-04695	Plasma	19-01-2024	Negative	22/03/2024	0.3098130 41	Negative	18/03/202 4	N/A
S112	DR-04702	Plasma	08-01-2024	Negative	22/03/2024	0.2294911 42	Negative	18/03/202 4	N/A
S114	DR-04717	Plasma	18-01-2024	Negative	22/03/2024	0.3488265 35	Negative	18/03/202 4	N/A
S117	DR-04722	Plasma	20-01-2024	Negative	22/03/2024	0.7802698 82	Negative	18/03/202 4	N/A
S120	DR-04734	Plasma	14-01-2024	Negative	22/03/2024	0.9340289 46	Negative	18/03/202 4	N/A
S122	DR-04740	Plasma	21-01-2024	Negative	22/03/2024	0.7710902 36	Negative	18/03/202 4	N/A
S123	DR-04741	Plasma	17-01-2024	Negative	22/03/2024	0.4314433 46	Negative	18/03/202 4	N/A
P49	DR-04745	Plasma	23-07-2023	Negative	19/03/2024	0.8835164 84	Negative	11/03/202 4	N/A
P48	DR-04748	Plasma	07-08-2023	Positive	19/03/2024	1.0285714 29	Weakly Positive	11/03/202 4	N/A
P47	DR-04765	Plasma	23-07-2023	Positive	19/03/2024	1.0813186 81	Weakly Positive	11/03/202 4	N/A
S121	DR-04807	Plasma	15-01-2024	Negative	22/03/2024	0.4979957 77	Negative	18/03/202 4	N/A
S118	DR-04817	Plasma	20-01-2024	Negative	22/03/2024	0.8169884 64	Negative	18/03/202 4	N/A
S119	DR-04836	Plasma	20-01-2024	Negative	22/03/2024	0.7642055 02	Negative	18/03/202 4	N/A
P46	DR-04840	Plasma	23-07-2023	Positive	19/03/2024	1.2527472 53	Weakly Positive	11/03/202 4	N/A
S116	DR-04841	Plasma	20-01-2024	Negative	22/03/2024	0.9959915 55	Negative	18/03/202 4	N/A
S115	DR-04846	Plasma	20-01-2024	Negative	22/03/2024	0.3212875 98	Negative	18/03/202 4	N/A
S113	DR-04862	Plasma	20-01-2024	Negative	22/03/2024	0.6632293 99	Negative	18/03/202 4	N/A
S111	DR-04863	Plasma	16-01-2024	Negative	22/03/2024	0.2111318 5	Negative	18/03/202 4	N/A
S110	DR-04872	Plasma	08-01-2024	Negative	22/03/2024	0.1629387 11	Negative	18/03/202 4	N/A
S103	DR-04881	Plasma	08-01-2024	Negative	22/03/2024	0.2065420 27	Negative	18/03/202 4	N/A
S105	DR-04914	Plasma	08-01-2024	Negative	22/03/2024	0.4475077 26	Negative	18/03/202 4	N/A
S107	DR-04916	Plasma	15-01-2024	Negative	22/03/2024	0.3098130 41	Negative	18/03/202 4	N/A

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P44	DR-04918	Plasma	23-07-2023	Positive	19/03/2024	2.3604395 6	Positive	11/03/202 4	N/A
S95	DR-04922	Plasma	19-01-2024	Negative	22/03/2024	0.6517548 42	Negative	18/03/202 4	N/A
S96	DR-04927	Plasma	16-09-2023	Negative	22/03/2024	0.3029283 07	Negative	18/03/202 4	N/A
S98	DR-04928	Plasma	16-09-2023	Negative	22/03/2024	0.5691380 31	Negative	18/03/202 4	N/A
S100	DR-04934	Plasma	08-01-2024	Negative	22/03/2024	0.3006333 96	Negative	18/03/202 4	N/A
S102	DR-04943	Plasma	18-01-2024	Negative	22/03/2024	0.2455555 22	Negative	18/03/202 4	N/A
S125	DR-04975	Plasma	21-01-2024	Negative	22/03/2024	0.5002906 89	Negative	18/03/202 4	N/A
S126	DR-04994	Plasma	08-01-2024	Negative	22/03/2024	0.3189926 87	Negative	18/03/202 4	N/A
S127	DR-05008	Plasma	21-01-2024	Negative	22/03/2024	0.6173311 71	Negative	18/03/202 4	N/A
S130	DR-05009	Plasma	21-01-2024	Negative	22/03/2024	0.8582968 7	Negative	18/03/202 4	N/A
S131	DR-05025	Plasma	21-01-2024	Negative	22/03/2024	0.2845690 16	Negative	18/03/202 4	N/A
S133	DR-05043	Plasma	21-01-2024	Negative	22/03/2024	0.3281723 33	Negative	18/03/202 4	N/A
S124	DR-05049	Plasma	21-01-2024	Negative	22/03/2024	0.5415990 94	Negative	18/03/202 4	N/A
S128	DR-05076	Plasma	11-01-2024	Negative	22/03/2024	0.3121079 53	Negative	18/03/202 4	N/A
S129	DR-05080	Plasma	21-01-2024	Negative	22/03/2024	0.5829075	Negative	18/03/202 4	N/A
S132	DR-05091	Plasma	21-01-2024	Negative	22/03/2024	0.7848597 04	Negative	18/03/202 4	N/A
S134	DR-05098	Plasma	21-01-2024	Negative	22/03/2024	0.3258774 21	Negative	18/03/202 4	N/A
S135	DR-05099	Plasma	07-01-2024	Negative	22/03/2024	0.1881827 36	Negative	18/03/202 4	N/A
S136	DR-05103	Plasma	12-01-2024	Negative	22/03/2024	0.7091276 28	Negative	18/03/202 4	N/A
S137	DR-05107	Plasma	21-01-2024	Negative	22/03/2024	0.1376946 85	Negative	18/03/202 4	N/A
S138	DR-05119	Plasma	20-01-2024	Negative	22/03/2024	0.4819313 97	Negative	18/03/202 4	N/A
S140	DR-05130	Plasma	08-01-2024	Negative	22/03/2024	0.8950154 52	Negative	18/03/202 4	N/A
S142	DR-05156	Plasma	10-01-2024	Negative	22/03/2024	0.6311006 4	Negative	18/03/202 4	N/A
S82	DR-05195	Plasma	14-09-2023	Negative	22/03/2024	0.1824034 33	Negative	12/03/202 4	N/A
S139	DR-05196	Plasma	21-01-2024	Negative	22/03/2024	0.9845169 98	Negative	18/03/202 4	N/A
S141	DR-05200	Plasma	09-01-2024	Negative	22/03/2024	0.1560539 76	Negative	18/03/202 4	N/A

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S143	DR-05201	Plasma	09-01-2024	Negative	22/03/2024	0.2203114 96	Negative	18/03/202 4	N/A
P50	DR-05207	Plasma	09-09-2023	Positive	19/03/2024	1.1340659 34	Weakly Positive	11/03/202 4	Type 4
S144	DR-05216	Plasma	13-01-2024	Negative	22/03/2024	0.1927725 59	Negative	18/03/202 4	N/A
S145	DR-05223	Plasma	09-01-2024	Negative	22/03/2024	0.2868639 27	Negative	18/03/202 4	N/A
S146	DR-05228	Plasma	14-01-2024	Negative	22/03/2024	0.1629387 11	Negative	18/03/202 4	N/A
S147	DR-05262	Plasma	09-01-2024	Negative	22/03/2024	0.1996572 93	Negative	18/03/202 4	N/A
S148	DR-05278	Plasma	10-01-2024	Negative	22/03/2024	0.2776842 81	Negative	18/03/202 4	N/A
S149	DR-05280	Plasma	10-01-2024	Negative	22/03/2024	0.2409656 99	Negative	18/03/202 4	N/A
S150	DR-05282	Plasma	19-01-2024	Negative	22/03/2024	0.3006333 96	Negative	18/03/202 4	N/A
S151	DR-05284	Plasma	08-01-2024	Negative	22/03/2024	0.2249013 19	Negative	18/03/202 4	N/A
S152	DR-05308	Plasma	10-01-2024	Negative	22/03/2024	0.3717756 49	Negative	18/03/202 4	N/A
S153	DR-05349	Plasma	12-01-2024	Negative	22/03/2024	0.1767081 79	Negative	18/03/202 4	N/A
S154	DR-05355	Plasma	10-01-2024	Negative	22/03/2024	0.2226064 07	Negative	18/03/202 4	N/A
S155	DR-05357	Plasma	10-01-2024	Negative	22/03/2024	0.2501453 44	Negative	18/03/202 4	N/A
S156	DR-05400	Plasma	14-01-2024	Negative	22/03/2024	0.3648909 15	Negative	18/03/202 4	N/A
S157	DR-05402	Plasma	16-01-2024	Negative	22/03/2024	0.2409656 99	Negative	18/03/202 4	N/A
S158	DR-05415	Plasma	16-01-2024	Negative	22/03/2024	0.1583488 88	Negative	18/03/202 4	N/A
P51	DR-05423	Plasma	20-07-2023	Positive	19/03/2024	1.0417582 42	Weakly Positive	11/03/202 4	N/A
P52	DR-05429	Plasma	21-07-2023	Positive	19/03/2024	1.2131868 13	Weakly Positive	11/03/202 4	N/A
P53	DR-05430	Plasma	21-07-2023	Positive	19/03/2024	1.1076923 08	Weakly Positive	11/03/202 4	N/A
P54	DR-05435	Plasma	21-07-2023	Positive	19/03/2024	3.8901098 9	Strongly Positive	11/03/202 4	Type 6
P55	DR-05440	Plasma	25-10-2023	Positive	19/03/2024	1.3846153 85	Weakly Positive	11/03/202 4	N/A
S185	DR-05444	Plasma	14-01-2024	Negative	22/03/2024	0.3102131 72	Negative	20/03/202 4	N/A
S159	DR-05493	Plasma	08-01-2024	Negative	22/03/2024	0.2249013 19	Negative	18/03/202 4	N/A
S160	DR-05497	Plasma	16-01-2024	Negative	22/03/2024	0.2340809 64	Negative	18/03/202 4	N/A
S161	DR-05520	Plasma	16-01-2024	Negative	22/03/2024	0.1491692 42	Negative	18/03/202 4	N/A

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S162	DR-05528	Plasma	15-01-2024	Negative	22/03/2024	0.3855451 18	Negative	18/03/202 4	N/A
S163	DR-05536	Plasma	10-01-2024	Negative	22/03/2024	0.2111318 5	Negative	18/03/202 4	N/A
S164	DR-05554	Plasma	17-01-2024	Negative	22/03/2024	0.2042471 16	Negative	18/03/202 4	N/A
P56	DR-05570	Plasma	21-07-2023	Positive	19/03/2024	1.6483516 48	Weakly Positive	11/03/202 4	N/A
S165	DR-05576	Plasma	10-01-2024	Negative	22/03/2024	0.2570300 79	Negative	18/03/202 4	N/A
S166	DR-05582	Plasma	17-01-2024	Negative	22/03/2024	0.1927725 59	Negative	18/03/202 4	N/A
S167	DR-05591	Plasma	17-01-2024	Negative	22/03/2024	0.1835929 13	Negative	18/03/202 4	N/A
S168	DR-05595	Plasma	09-01-2024	Negative	22/03/2024	0.1744132 68	Negative	18/03/202 4	N/A
S169	DR-05603	Plasma	17-01-2024	Negative	22/03/2024	0.1698234 45	Negative	18/03/202 4	N/A
S170	DR-05606	Plasma	17-01-2024	Negative	22/03/2024	0.1881827 36	Negative	18/03/202 4	N/A
S171	DR-05607	Plasma	19-01-2024	Negative	22/03/2024	0.1881827 36	Negative	18/03/202 4	N/A
S172	DR-05625	Plasma	07-01-2024	Negative	22/03/2024	0.3373519 78	Negative	18/03/202 4	N/A
S173	DR-05671	Plasma	20-01-2024	Negative	22/03/2024	0.3511214 47	Negative	18/03/202 4	N/A
S174	DR-05674	Plasma	12-01-2024	Negative	22/03/2024	0.8743612 5	Negative	18/03/202 4	N/A
S175	DR-05675	Plasma	12-01-2024	Negative	22/03/2024	0.1790030 9	Negative	18/03/202 4	N/A
S176	DR-05680	Plasma	09-01-2024	Negative	22/03/2024	0.6265108 17	Negative	18/03/202 4	N/A
S177	DR-05689	Plasma	10-01-2024	Negative	22/03/2024	0.2983384 84	Negative	18/03/202 4	N/A
S178	DR-05701	Plasma	12-01-2024	Negative	22/03/2024	0.3442367 12	Negative	18/03/202 4	N/A
P57	DR-05703	Plasma	21-07-2023	Positive	03/06/2024	1.0457656 12	Positive	30/05/202 4	N/A
S179	DR-05705	Plasma	13-01-2024	Negative	22/03/2024	0.2524402 56	Negative	18/03/202 4	N/A
S180	DR-05741	Plasma	13-01-2024	Negative	22/03/2024	0.1835929 13	Negative	18/03/202 4	N/A
S181	DR-05743	Plasma	08-01-2024	Negative	22/03/2024	0.6861785 14	Negative	18/03/202 4	N/A
S182	DR-05744	Plasma	13-01-2024	Negative	22/03/2024	0.2271962 3	Negative	18/03/202 4	N/A
S183	DR-05746	Plasma	13-01-2024	Negative	22/03/2024	0.2099904 55	Negative	20/03/202 4	N/A
S184	DR-05747	Plasma	13-01-2024	Negative	22/03/2024	0.2004454 34	Negative	20/03/202 4	N/A
P58	DR-05750	Plasma	21-07-2023	Positive	19/03/2024	1.4769230 77	Weakly Positive	11/03/202 4	Type 4

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S186	DR-05752	Plasma	14-01-2024	Negative	22/03/2024	0.2362392 62	Negative	20/03/2024 4	N/A
S187	DR-05773	Plasma	14-01-2024	Negative	22/03/2024	0.1861279 03	Negative	20/03/2024 4	N/A
S188	DR-05776	Plasma	14-01-2024	Negative	22/03/2024	0.5965637 93	Negative	20/03/2024 4	N/A
S189	DR-05777	Plasma	14-01-2024	Negative	22/03/2024	0.2935093 86	Negative	20/03/2024 4	N/A
S190	DR-05779	Plasma	14-01-2024	Negative	22/03/2024	0.2195354 76	Negative	20/03/2024 4	N/A
S191	DR-05780	Plasma	14-01-2024	Negative	22/03/2024	0.2099904 55	Negative	20/03/2024 4	N/A
S192	DR-05781	Plasma	15-01-2024	Negative	22/03/2024	0.1360165 45	Negative	20/03/2024 4	N/A
S193	DR-05818	Plasma	18-01-2024	Negative	22/03/2024	0.2123767 1	Negative	20/03/2024 4	N/A
S194	DR-05828	Plasma	15-01-2024	Negative	22/03/2024	0.2219217 31	Negative	20/03/2024 4	N/A
S195	DR-05836	Plasma	14-01-2024	Negative	22/03/2024	0.2195354 76	Negative	20/03/2024 4	N/A
S196	DR-05862	Plasma	08-01-2024	Negative	22/03/2024	0.2123767 1	Negative	20/03/2024 4	N/A
S197	DR-05923	Plasma	08-01-2024	Negative	22/03/2024	0.1479478 21	Negative	20/03/2024 4	N/A
S198	DR-05960	Plasma	07-01-2024	Negative	22/03/2024	0.1694241 17	Negative	20/03/2024 4	N/A
S199	DR-05989	Plasma	11-01-2024	Negative	22/03/2024	0.5106586 06	Negative	20/03/2024 4	N/A
S200	DR-05996	Plasma	15-01-2024	Negative	22/03/2024	0.2982818 96	Negative	20/03/2024 4	N/A
P59	DR-06354	Plasma	12-10-2023	Positive	19/03/2024	1.3450549 45	Weakly Positive	11/03/2024 4	N/A
P60	DR-06362	Plasma	12-10-2023	Positive	19/03/2024	1.5428571 43	Weakly Positive	11/03/2024 4	Type 4
P61	DR-06432	Plasma	22-07-2023	Positive	19/03/2024	1.1472527 47	Weakly Positive	11/03/2024 4	N/A
P62	DR-06455	Plasma	25-10-2023	Positive	19/03/2024	1.2659340 66	Weakly Positive	11/03/2024 4	N/A
P63	DR-06496	Plasma	09-12-2023	Positive	19/03/2024	1.1076923 08	Weakly Positive	11/03/2024 4	Type 4
P64	DR-07081	Plasma	24-11-2023	Positive	19/03/2024	1.3186813 19	Weakly Positive	11/03/2024 4	N/A
P65	DR-07120	Plasma	26-07-2023	Negative	19/03/2024	0.8703296 7	Negative	11/03/2024 4	N/A
P66	DR-07168	Plasma	26-07-2023	Positive	19/03/2024	1.1736263 74	Weakly Positive	11/03/2024 4	N/A
P67	DR-07172	Plasma	15-12-2023	Positive	19/03/2024	1.5692307 69	Weakly Positive	11/03/2024 4	N/A
P68	DR-07182	Plasma	08-01-2024	Positive	19/03/2024	2.1758241 76	Positive	11/03/2024 4	N/A
S277	DR-07237	Plasma	15-09-2023	Negative	22/03/2024	0.1824034 33	Negative	12/03/2024 4	N/A

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P69	DR-07302	Plasma	27-07-2023	Positive	19/03/2024	3.9296703 3	Strongly Positive	11/03/202 4	N/A
P70	DR-07309	Plasma	27-07-2023	Positive	19/03/2024	1.4109890 11	Weakly Positive	11/03/202 4	N/A
P71	DR-07318	Plasma	07-01-2024	Positive	19/03/2024	1.4109890 11	Weakly Positive	11/03/202 4	N/A
P72	DR-07345	Plasma	27-07-2023	Positive	19/03/2024	1.2527472 53	Weakly Positive	11/03/202 4	N/A
P73	DR-07354	Plasma	16-01-2024	Negative	19/03/2024	0.8175824 18	Negative	11/03/202 4	N/A
P74	DR-07403	Plasma	28-07-2023	Positive	19/03/2024	1.1604395 6	Weakly Positive	11/03/202 4	N/A
P75	DR-07578	Plasma	28-07-2023	Positive	19/03/2024	1.1736263 74	Weakly Positive	11/03/202 4	N/A
P76	DR-07593	Plasma	28-07-2023	Positive	19/03/2024	1.2	Weakly Positive	11/03/202 4	N/A
P77	DR-08167	Plasma	12-04-2023	Positive	19/03/2024	1.1208791 21	Weakly Positive	11/03/202 4	N/A
P78	DR-08269	Plasma	01-08-2023	Positive	19/03/2024	1.1208791 21	Weakly Positive	11/03/202 4	N/A
P79	DR-08314	Plasma	02-08-2023	Positive	19/03/2024	1.4373626 37	Weakly Positive	11/03/202 4	N/A
P80	DR-08333	Plasma	03-08-2023	Positive	19/03/2024	1.2791208 79	Weakly Positive	11/03/202 4	N/A
P81	DR-08334	Plasma	19-04-2023	Positive	19/03/2024	2.0043956 04	Positive	11/03/202 4	N/A
P82	DR-08365	Plasma	10-01-2024	Positive	19/03/2024	1.1208791 21	Weakly Positive	11/03/202 4	Type 4
P83	DR-08473	Plasma	03-08-2023	Positive	19/03/2024	1.2791208 79	Weakly Positive	11/03/202 4	N/A
P84	DR-08897	Plasma	03-08-2023	Positive	19/03/2024	1.3450549 45	Weakly Positive	11/03/202 4	N/A
P85	DR-09052	Plasma	03-08-2023	Positive	19/03/2024	1.1868131 87	Weakly Positive	11/03/202 4	Type 4
P86	DR-09078	Plasma	26-05-2023	Positive	19/03/2024	1.2527472 53	Weakly Positive	11/03/202 4	Type 4
P87	DR-09080	Plasma	03-08-2023	Positive	19/03/2024	1.2000000 00	Weakly Positive	11/03/202 4	N/A
P88	DR-09082	Plasma	04-08-2023	Positive	19/03/2024	2.3340659 34	Positive	11/03/202 4	N/A
P183	DR-09451	Plasma	28-08-2023	Positive	19/03/2024	1.0458897 33	Weakly Positive	19/03/202 4	N/A
P184	DR-09688	Plasma	10-09-2023	Positive	03/06/2024	1.3665526 09	Positive	30/05/202 4	N/A
P185	DR-09778	Plasma	29-08-2023	Positive	19/03/2024	1.5450643 78	Weakly Positive	19/03/202 4	Type 4
P186	DR-09881	Plasma	29-08-2023	Positive	19/03/2024	1.1766259 49	Weakly Positive	19/03/202 4	N/A
P89	DR-09923	Plasma	04-08-2023	Positive	19/03/2024	1.1208791 21	Weakly Positive	11/03/202 4	N/A
P90	DR-09944	Plasma	10-01-2024	Positive	19/03/2024	1.0549450 55	Weakly Positive	11/03/202 4	N/A



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P91	DR-09951	Plasma	07-04-2023	Positive	19/03/2024	1.0681318 68	Weakly Positive	11/03/202 4	N/A
P92	DR-10043	Plasma	04-08-2023	Positive	19/03/2024	1.5943952 8	Weakly Positive	13/03/202 4	N/A
P93	DR-10116	Plasma	04-08-2023	Positive	19/03/2024	1.5039331 37	Weakly Positive	13/03/202 4	N/A
P94	DR-10132	Plasma	07-08-2023	Positive	19/03/2024	1.2551622 42	Weakly Positive	13/03/202 4	N/A
P110	DR-10159	Plasma	10-08-2023	Negative	19/03/2024	0.8028515 24	Negative	13/03/202 4	N/A
P95	DR-10292	Plasma	07-08-2023	Positive	19/03/2024	3.2114060 96	Positive	13/03/202 4	N/A
P96	DR-10310	Plasma	28-05-2023	Positive	19/03/2024	1.4926253 69	Weakly Positive	13/03/202 4	N/A
P97	DR-10333	Plasma	07-08-2023	Positive	19/03/2024	5.1111111 11	Strongly Positive	13/03/202 4	N/A
P98	DR-10342	Plasma	07-08-2023	Positive	19/03/2024	2.8043264 5	Positive	13/03/202 4	Type 5
P99	DR-10345	Plasma	12-04-2023	Positive	19/03/2024	1.6509341 2	Weakly Positive	13/03/202 4	N/A
P100	DR-10401	Plasma	08-08-2023	Positive	19/03/2024	1.4813176 01	Weakly Positive	13/03/202 4	N/A
P101	DR-10402	Plasma	08-08-2023	Positive	19/03/2024	1.1647000 98	Weakly Positive	13/03/202 4	N/A
P102	DR-10450	Plasma	23-06-2023	Positive	19/03/2024	1.2099311 7	Weakly Positive	13/03/202 4	N/A
P106	DR-10503	Plasma	06-09-2023	Positive	19/03/2024	2.1032448 38	Positive	13/03/202 4	N/A
P107	DR-10521	Plasma	10-08-2023	Positive	19/03/2024	1.5265486 73	Weakly Positive	13/03/202 4	N/A
P108	DR-10558	Plasma	21-09-2023	Positive	19/03/2024	2.5781710 91	Positive	13/03/202 4	N/A
P112	DR-10603	Plasma	07-06-2023	Positive	19/03/2024	1.1307767 94	Weakly Positive	13/03/202 4	N/A
P105	DR-10606	Plasma	08-08-2023	Positive	19/03/2024	2.2050147 49	Positive	13/03/202 4	N/A
P111	DR-10650	Plasma	10-08-2023	Positive	19/03/2024	1.0403146 51	Weakly Positive	13/03/202 4	N/A
P109	DR-10670	Plasma	23-05-2023	Positive	19/03/2024	1.5265486 73	Weakly Positive	13/03/202 4	Type 4
P103	DR-10912	Plasma	20-07-2023	Positive	19/03/2024	1.0176991 15	Weakly Positive	13/03/202 4	N/A
P104	DR-10990	Plasma	20-06-2023	Positive	19/03/2024	2.2728613 57	Positive	13/03/202 4	N/A
P113	DR-11231	Plasma	11-08-2023	Positive	19/03/2024	7.7910521 14	Strongly Positive	13/03/202 4	N/A
P114	DR-11245	Plasma	19-06-2023	Positive	19/03/2024	1.7187807 28	Weakly Positive	13/03/202 4	N/A
P115	DR-11254	Plasma	09-05-2023	Positive	19/03/2024	1.5830875 12	Weakly Positive	13/03/202 4	N/A
P122	DR-11352	Plasma	12-08-2023	Positive	19/03/2024	3.7994100 29	Strongly Positive	13/03/202 4	N/A

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P121	DR-11359	Plasma	12-08-2023	Positive	19/03/2024	2.4537856 44	Positive	13/03/202 4	N/A
P120	DR-11363	Plasma	05-12-2023	Positive	19/03/2024	4.6022615 54	Strongly Positive	13/03/202 4	Type 5
P119	DR-11389	Plasma	11-08-2023	Positive	19/03/2024	3.7654867 26	Strongly Positive	13/03/202 4	N/A
P118	DR-11395	Plasma	11-08-2023	Positive	19/03/2024	4.0255653 88	Strongly Positive	13/03/202 4	N/A
P117	DR-11629	Plasma	27-09-2023	Positive	19/03/2024	3.8446411 01	Strongly Positive	13/03/202 4	N/A
P116	DR-11698	Plasma	11-08-2023	Positive	19/03/2024	4.9075712 88	Strongly Positive	13/03/202 4	Type 4
P124	DR-12235	Plasma	12-08-2023	Positive	19/03/2024	6.1740412 98	Strongly Positive	13/03/202 4	Type 6
P123	DR-12344	Plasma	12-08-2023	Positive	19/03/2024	2.1258603 74	Positive	13/03/202 4	N/A
P125	DR-12470	Plasma	12-08-2023	Positive	19/03/2024	2.4650934 12	Positive	13/03/202 4	N/A
P126	DR-12472	Plasma	13-08-2023	Positive	19/03/2024	1.5717797 44	Weakly Positive	13/03/202 4	Type 4
P127	DR-12496	Plasma	23-12-2023	Positive	19/03/2024	3.0417895 77	Strongly Positive	13/03/202 4	N/A
P128	DR-12554	Plasma	13-08-2023	Positive	19/03/2024	1.5378564 41	Weakly Positive	13/03/202 4	N/A
P129	DR-12622	Plasma	13-08-2023	Positive	19/03/2024	6.3549655 85	Strongly Positive	13/03/202 4	Type 6
P130	DR-12623	Plasma	07-01-2023	Positive	19/03/2024	4.2291052 11	Strongly Positive	13/03/202 4	Type 4
P134	DR-12831	Plasma	16-01-2023	Positive	19/03/2024	1.6057030 48	Weakly Positive	13/03/202 4	N/A
P137	DR-12839	Plasma	15-08-2023	Negative	19/03/2024	0.6784660 77	Negative	13/03/202 4	N/A
P133	DR-12933	Plasma	15-08-2023	Positive	19/03/2024	1.6170108 16	Weakly Positive	13/03/202 4	N/A
P136	DR-12969	Plasma	08-02-2023	Positive	19/03/2024	14.801868 24	Strongly Positive	13/03/202 4	N/A
P139	DR-12975	Plasma	15-08-2023	Positive	19/03/2024	4.8510324 48	Strongly Positive	13/03/202 4	Type 4
P131	DR-12984	Plasma	13-08-2023	Positive	19/03/2024	1.4021632 25	Weakly Positive	13/03/202 4	N/A
P132	DR-13002	Plasma	13-08-2023	Positive	19/03/2024	3.8672566 37	Strongly Positive	13/03/202 4	N/A
P138	DR-13013	Plasma	15-08-2023	Positive	19/03/2024	2.3746312 68	Positive	13/03/202 4	N/A
P135	DR-13038	Plasma	15-08-2023	Positive	03/06/2024	1.0134730 54	Positive	30/05/202 4	N/A
P140	DR-13110	Plasma	27-03-2023	Positive	19/03/2024	4.4100294 99	Strongly Positive	13/03/202 4	Type 5
P141	DR-13141	Plasma	16-08-2023	Negative	19/03/2024	0.7689282 2	Negative	13/03/202 4	N/A
P142	DR-13255	Plasma	16-08-2023	Positive	19/03/2024	3.1096361 85	Positive	13/03/202 4	N/A

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P193	DR-13479	Plasma	06-09-2023	Positive	19/03/2024	1.0577748 43	Weakly Positive	19/03/202 4	N/A
P143	DR-13688	Plasma	16-08-2023	Positive	19/03/2024	1.0855457 23	Weakly Positive	13/03/202 4	N/A
P144	DR-13710	Plasma	16-08-2023	Positive	03/06/2024	1.0307955 52	Positive	30/05/202 4	N/A
P145	DR-13730	Plasma	10-08-2023	Positive	19/03/2024	1.4134709 93	Weakly Positive	13/03/202 4	N/A
P146	DR-13749	Plasma	16-08-2023	Negative	19/03/2024	0.8028515 24	Negative	13/03/202 4	N/A
P147	DR-13770	Plasma	23-08-2023	Positive	03/06/2024	1.0008554 32	Positive	30/05/202 4	N/A
P148	DR-13848	Plasma	23-08-2023	Positive	19/03/2024	1.3682399 21	Weakly Positive	13/03/202 4	N/A
P149	DR-13922	Plasma	23-08-2023	Positive	19/03/2024	1.1873156 34	Weakly Positive	13/03/202 4	Type 4
P150	DR-13956	Plasma	23-08-2023	Positive	19/03/2024	1.4813176 01	Weakly Positive	13/03/202 4	N/A
P151	DR-14101	Plasma	21-08-2023	Positive	19/03/2024	1.1081612 59	Weakly Positive	13/03/202 4	N/A
P152	DR-14110	Plasma	21-08-2023	Positive	19/03/2024	1.8318584 07	Weakly Positive	13/03/202 4	N/A
P153	DR-14115	Plasma	19-05-2023	Negative	19/03/2024	0.8706981 32	Negative	13/03/202 4	N/A
P154	DR-14120	Plasma	08-06-2023	Positive	19/03/2024	1.0968534 91	Weakly Positive	13/03/202 4	N/A
P155	DR-14203	Plasma	21-08-2023	Positive	19/03/2024	1.2325467 06	Weakly Positive	13/03/202 4	N/A
P156	DR-14227	Plasma	21-08-2023	Positive	19/03/2024	1.7979351 03	Weakly Positive	13/03/202 4	N/A
P157	DR-14267	Plasma	21-08-2023	Positive	19/03/2024	1.1873156 34	Weakly Positive	13/03/202 4	N/A
P158	DR-14449	Plasma	21-08-2023	Negative	19/03/2024	0.7802359 88	Negative	13/03/202 4	N/A
P159	DR-14457	Plasma	21-08-2023	Positive	19/03/2024	1.1081612 59	Weakly Positive	13/03/202 4	N/A
P160	DR-14513	Plasma	06-07-2023	Positive	19/03/2024	1.1533923 3	Weakly Positive	13/03/202 4	N/A
P161	DR-14776	Plasma	22-08-2023	Negative	19/03/2024	0.7350049 16	Negative	13/03/202 4	N/A
P162	DR-14806	Plasma	22-08-2023	Positive	19/03/2024	1.8997050 15	Weakly Positive	13/03/202 4	N/A
P163	DR-14897	Plasma	22-08-2023	Positive	19/03/2024	1.0403146 51	Weakly Positive	13/03/202 4	N/A
P164	DR-14912	Plasma	22-08-2023	Positive	19/03/2024	1.0063913 47	Weakly Positive	13/03/202 4	Type 4
P165	DR-15175	Plasma	22-08-2023	Negative	19/03/2024	1.2664700 1	Weakly Positive	13/03/202 4	N/A
P166	DR-15199	Plasma	23-08-2023	Positive	03/06/2024	1.3088109 5	Positive	30/05/202 4	N/A
P167	DR-15241	Plasma	23-08-2023	Positive	03/06/2024	1.6766467 07	Positive	30/05/202 4	N/A

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P168	DR-15305	Plasma	23-08-2023	Negative	19/03/2024	0.8593903 64	Negative	13/03/202 4	N/A
P169	DR-15307	Plasma	23-08-2023	Negative	19/03/2024	0.8367748 28	Negative	13/03/202 4	N/A
P170	DR-15567	Plasma	23-08-2023	Positive	03/06/2024	1.3943541 49	Positive	30/05/202 4	N/A
P171	DR-15653	Plasma	23-08-2023	Positive	03/06/2024	1.1591103 51	Positive	30/05/202 4	N/A
P172	DR-16018	Plasma	07-09-2023	Negative	19/03/2024	1.6622418 88	Weakly Positive	13/03/202 4	N/A
P173	DR-16024	Plasma	15-08-2023	Positive	19/03/2024	1.7300884 96	Weakly Positive	13/03/202 4	N/A
P174	DR-16048	Plasma	14-09-2023	Positive	19/03/2024	4.3082595 87	Strongly Positive	13/03/202 4	Type 4
P175	DR-16050	Plasma	19-10-2023	Positive	03/06/2024	1.0307955 52	Positive	30/05/202 4	N/A
P192	DR-16163	Plasma	01-09-2023	Negative	19/03/2024	0.6774513 04	Negative	19/03/202 4	N/A
P176	DR-16253	Plasma	24-08-2023	Positive	19/03/2024	3.0870206 49	Positive	13/03/202 4	N/A
P177	DR-16307	Plasma	25-08-2023	Positive	19/03/2024	1.4700098 33	Weakly Positive	13/03/202 4	N/A
P178	DR-16340	Plasma	25-08-2023	Positive	19/03/2024	1.6961651 92	Weakly Positive	13/03/202 4	N/A
P179	DR-16352	Plasma	25-08-2023	Positive	19/03/2024	1.2438544 74	Weakly Positive	13/03/202 4	N/A
P187	DR-16363	Plasma	29-08-2023	Positive	03/06/2024	1.1377245 51	Positive	30/05/202 4	N/A
P188	DR-16463	Plasma	28-10-2023	Positive	19/03/2024	16.627269 73	Strongly Positive	19/03/202 4	Type 4
P189	DR-16479	Plasma	30-08-2023	Positive	19/03/2024	1.4618686 03	Weakly Positive	19/03/202 4	N/A
P191	DR-16663	Plasma	01-09-2023	Positive	19/03/2024	1.0458897 33	Weakly Positive	19/03/202 4	N/A
P190	DR-16920	Plasma	31-08-2023	Positive	19/03/2024	1.0934301 75	Weakly Positive	19/03/202 4	Type 4
P194	DR-16921	Plasma	06-09-2023	Positive	19/03/2024	1.1053152 86	Weakly Positive	19/03/202 4	N/A
P196	DR-16945	Plasma	06-09-2023	Positive	19/03/2024	1.0577748 43	Weakly Positive	19/03/202 4	N/A
P195	DR-16949	Plasma	06-09-2023	Positive	19/03/2024	1.0934301 75	Weakly Positive	19/03/202 4	N/A
P180	DR-16975	Plasma	07-09-2023	Positive	03/06/2024	1.2874251 5	Positive	30/05/202 4	N/A
P181	DR-17014	Plasma	09-09-2023	Positive	19/03/2024	37.304326 45	Strongly Positive	13/03/202 4	Type 4
P197	DR-17114	Plasma	06-09-2023	Negative	19/03/2024	0.7368768 57	Negative	19/03/202 4	N/A
P182	DR-17414	Plasma	26-08-2023	Positive	19/03/2024	1.1194690 27	Weakly Positive	13/03/202 4	N/A
P198	DR-17417	Plasma	06-09-2023	Negative	19/03/2024	0.8438428 52	Negative	19/03/202 4	N/A

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P199	DR-17518	Plasma	06-09-2023	Positive	19/03/2024	1.8421921 43	Weakly Positive	19/03/202 4	N/A
P200	DR-17872	Plasma	23-09-2023	Positive	19/03/2024	2.2819412 35	Positive	19/03/202 4	Type 6

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**Table 5** Showing Statistical Analysis in a fourfold table for evaluation of the HCV Rapid test.

HCV All Specimens		Predicate Device		Total Results
Candidate Device	Results	Positive	Negative	
Candidate Device	Positive	178	0	178
	Negative	0	222	222
	Total Results	178	222	400
	Relative sensitivity	100.00% [97.95%;100.00%]		
Relative specificity	100.00% [98.35%;100.00%]			
Accuracy	100.00% [99.08%; 100.00%]			
Kappa	1 [1; 1]			

Relative sensitivity=  $[178 / (178+0)] \times 100 = 100\%$

Relative specificity=  $[222 / (0+222)] \times 100 = 100\%$

Overall accuracy=  $[(178+222) / (178+0+0+222)] \times 100 = 100\%$

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## **8 ANALYTICAL METHOD VALIDATION SUMMARY REPORT**

<b>Analytical Method validation Protocol Summary</b>			
<b>Ref. No.</b>	<b>Test Data Sheet Title</b>	<b>Result (Pass/Fail)</b>	
8.1	Analytical Method Validation Data	Pass	
8.1.1	Method Suitability and Performance	Pass	
8.1.2	Method Variability	Pass	
<b>Analytical Method Validation Report Summary</b>			
<b>Method Name</b>		<b>Type</b>	
HCV Rapid Test		Antibody detection of HCV	
<b>Validation Parameter</b>	<b>Requirements</b>	<b>Results (Approved / Rejected)</b>	<b>Pass/ Fail</b>
Method Suitability	HCV Rapid Test is suitable for its intended purpose.  i.e.) In terms of clinical diagnosis, the method suitability test confirms that the plasma sample is suitable for use.	Approved	Pass
Method Performance	HCV Rapid Test meets required performance criteria.  i.e.) Sensitivity is higher than 90% Specificity is higher than 90%"	Approved	Pass
Method Variability	Limited / insignificant variability observed	Approved	Pass
<b>Statement of Conformance:</b>			
√	The validation for this test method has been successfully completed.		
N/A	Notifications were raised due to discrepancies noted during execution. These have been resolved or have been noted for further action before closure of the validation report.		

# **ANALYTICAL METHOD VALIDATION and REPORT**

**Hangzhou Alltest Biotech Co.,Ltd**

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## **9 DISCUSSION AND CONCLUSION**

The results of this clinical performance study demonstrate that the HCV Rapid Test has excellent performance characteristics, achieving 100% diagnostic sensitivity, 100% diagnostic specificity and 100% Accuracy compared to the reference test (Monalisa Anti HCV Plus Version 3), with a Kappa value of 1. The inclusion of specimens from various HCV genotypes further validates the test's broad applicability and robustness. This ensures that the test can reliably detect HCV infection in diverse patient populations, contributing to effective clinical patient management of HCV infection.

Diagnostic sensitivity of the HCV Rapid Test was evaluated with 178 confirmed HCV-positive samples. The diagnostic sensitivity in this evaluation was identified to be 100% (Willson 95% CI: 97.95-100.00%), which fulfills the acceptance criteria stated in the Common Specifications Document. No limitation to the performance of HCV Rapid Test was identified in relation to different HCV genotype.

Diagnostic specificity of the HCV Rapid Test was evaluated with 222 samples from negative blood donors. The diagnostic specificity in this evaluation was identified to be 100% , Willson 95% CI: 98.35-100.00%, which fulfils the acceptance criteria stated in the CS ( $\geq 99\%$ ).Overall, HCV Rapid Test fulfils the requirements stated in the Common Specifications for class D devices, specifically Annex V Table 2 - Rapid tests: anti-HCV, HCV Ag/Ab (requirements for antibody detection).

All data obtained within this validation study met required specification and limited deviations or non-conformances were observed. The HCV Rapid test from Hangzhou Alltest Biotech Co.,Ltd met all requirements and is suitable for use as detection of antibody presence in HCV positive patients. The method and instrument in place is efficient in terms of accuracy, precision, repeatability, specificity and sensitivity therefore meets user requirements based on manufacturer's guidelines as previously validated.

To ensure high quality of the HCV plasma sample, it is recommended that for long storage, all the plasma samples were stored at  $-80^{\circ}\text{C}$  and reagents be stored at temperatures stated in the IFU to preserve integrity of the reagent and to avoid freeze thawing more than three times. Regular maintenance of the instruments is recommended, however based on usage, a planned preventative maintenance of the instrument may be arranged with the supplier. This is user specified. All reagents are stored at the relevant storage conditions based on manufacturers recommendations and used prior to expiration. All consumables used are sterile and nuclease free. Proper Personal protective equipment (PPE) is available on site and must be always worn by all personnel on site. Good laboratory practices are adhered to and maintained throughout all the facility. Trained laboratory staff with significant knowledge in molecular biology with specialised skillsets performed all laboratory testing for this validation.

—————End of Report—————



# **ANALYTICAL METHOD VALIDATION and REPORT**

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## **10 FINAL REPORT APPROVAL FORM**

This is to certify that the undersigned have reviewed this executed protocol and have found that all applicable requirements and criteria have been met.

### **Section 1: Reviewed and approved by**

<b>Company</b>	<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>
Rapid Diagnostics	Prof Veron Ramsuran	Senior Scientist		13 June 2024