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### Virology PT Program:

The Virology PT program is distributed 4 times per annum and includes the following test parameters : HIV, HBV, HCV, & TPHA.

Samples are produced by Donation Testing Department (DTD) and packaged and issued by the PT Coordinators. All batches are issued at the beginning of the cycle in February, and transported at ambient temperature. Participants are instructed to freeze samples on receipt until the batch is due for testing is received. These participants are from external organizations, there were no SANBS laboratories participating.

**Table 1: Batch information**

Batch	VIR01/22	VIR02/22
Date Issued	16/02/2022	11/05/2022
Due date	09/03/2022	25/05/2022
Report date	10/03/2022	07/06/2022

During packing of the samples the coordinators noticed that some of the samples leaked, and a notification was logged against DTD, refer to NC250036592. DTD produced another batch of samples (Batch 2 ) for the participants that could not be supplied from the original batch, ( Batch1) . VIR-01/22 and VIR02/22 for the year is complete and both had low participant compliance. See table 2

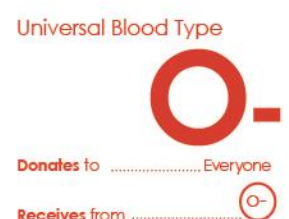
**Table2: Compliance for batches 1 &2**

	% Technical Compliance	% Overall Compliance	Non- submissions
Q1 ( VIR01/22)	86%	65%	24%
Q2 (VIR02/22)	91%	71%	22%
Q3			0%
Q4			0%
Total	89%	69%	23%

After the low compliance rate was noticed for VIR01/22, DTD was requested to retest retention samples and confirm results. A communication was sent to participants, requesting them to indicate the instrument used for testing. One laboratory also logged a compliant for incorrect labelling, NC 250037915.

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On release of the VIR02/22 report, similar low compliance was observed and a task team was assembled to investigate. Task team members included TN- PT Scheme Manager, JM- Senior Manager Operations testing, Head of QC, Operations Testing and Project manager, Virology Reference laboratory manager.

Samples were collected from the freezer, thawed and re-tested in SANBS

Samples were removed from freezer and sent to Lancet frozen for testing as the SANBS referral lab and because Lancet uses an Abbott instrument, similar to many of the participants

Samples were removed from freezer, kept at room temperature for 7 days, to mimic transportation conditions and then tested in SANBS.

Annexure 1 include all test results which include participant results, repeat results from SANBS and results obtained from Lancet.

#### **Result discussion:**

##### **HBV samples**

Repeat results from samples thawed and tested compared to original results and memorandum

Samples sent to Lancet compared to original results except for one HBV samples, VRHB02/22A from batch1, which tested positive instead of negative.

Samples stored at room temperature for 7 days prior to testing, gave results similar to the participants that failed.

##### **TPHA samples**

All repeat sample results compared to the original expected results.

##### **Conclusion:**

False positive results obtained by participants for HBV batches 1 and 2 can be the result of contamination, which appears to be related to cold chain prior to testing.

False negative results could have been caused by method limitation or deterioration.

#### **Recommendation for consideration by PAC:**

1. Results for VIR01/22 and VIR02/22 HBV samples to be made invalid
2. Replacement samples for HBV to be manufactured and issued to all participants for all 4 test events
3. Samples to be shipped on dry ice to prevent contamination and deterioration as far as possible.
4. Communication to be drafted to participants informing them of the replacement of the samples due to possible contamination



Truscha Niekerk

PT Scheme Manager

19/08/2022

## Annexure 1 :Results

Table 3: Participant Results and Method of Analysis (HBV Panel 1)

HBV	Participant	Method Of Analysis	VR-HB-01/22-A	VR-HB-01/22-B	VR-HB-01/22-C	VR-HB-01/22-D	VR-HB-01/22-E	VR-HB-01/22-F
VR01/22	SANBS PT	Panther	Positive	Positive	Negative	Positive	Negative	Negative
	June Batch (SANBS)	Panther	Positive	Positive	Negative	Positive	Negative	Negative
	Batch 1 (SANBS)	Panther	Positive	Positive	Negative	Positive	Negative	Negative
	Batch 2 (SANBS)	Panther	Positive	Positive	Negative	Positive	Negative	Negative
	Batch 1 (Lancet)	Abbott Architect i2000	Positive	Positive	Negative	Positive	Negative	Negative
	Batch 2 (Lancet)	Abbott Architect i2000	Positive	Positive	Negative	Positive	Negative	Negative
	Batch 1 Room Temperature	Panther	Positive	Positive	Positive	Positive	Negative	Negative
	Batch 2 Room Temperature	Panther	Positive	Positive	Negative	Positive	Negative	Negative
Batch 2	Eswatini	Abbott Architect i2000	Positive	Positive	Positive	Positive	Negative	Negative
Batch1	Malawi	Abbott Architect	Positive	Positive	Positive	Positive	Negative	Negative
Batch1	Namibia	Abbott Diagnostics	Positive	Positive	Positive	Positive	Positive	Negative
Batch1	Togo	Bio-Rad Monolisa	Positive	Positive	Positive	Negative	Positive	Positive
Batch 1	Zimbabwe	Abbott Architect i2000	Positive	Positive	Positive	Positive	Negative	Negative
Batch 1	Lesotho BTS	No Response	Positive	Positive	Negative	Positive	Negative	Positive
Batch1	Mauritius	No Response	Positive	Positive	Negative	Positive	Negative	Negative
Batch 1	Ghana	No response	Positive	Positive	Positive	Positive	Negative	Negative



Table 4: Participant Results and Method of Analysis (HBV Panel 2)

Extended Investigation								
HBV	Participant	Method Of Analysis	VR-HB-02/22-A	VR-HB-02/22-B	VR-HB-02/22-C	VR-HB-02/22-D	VR-HB-02/22-E	VR-HB-02/22-F
VR02/22	<b>SANBS PT</b>	<b>Panther</b>	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	<b>Negative</b>	<b>Negative</b>	<b>Positive</b>
	June Batch (SANBS)	Panther	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	<b>Negative</b>	<b>Negative</b>	<b>Positive</b>
	Batch 1 (SANBS)	Panther	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative	<b>Positive</b>
	Batch 2 (SANBS)	Panther	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative	<b>Positive</b>
	<b>Batch 1 (Lancet)</b>	<b>Abbott Architect i2000</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative	<b>Positive</b>
	Batch 2 (Lancet)	Abbott Architect i2000	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	Negative	<b>Negative</b>	<b>Positive</b>
	Room Temperature Batch 1	Panther	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>
	Room Temperature Batch 2	Panther	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	Negative	<b>Negative</b>	<b>Positive</b>
Batch 2	Eswatini	Abbott Architect i2000	Negative	<b>Positive</b>	<b>Positive</b>	Negative	Negative	<b>Positive</b>
Batch 1	Malawi	Abbott Architect	<b>Positive</b>	positive	Positive	<b>Positive</b>	<b>Positive</b>	Positive
Batch 1	Namibia	Abbott Diagnostics	<b>Positive</b>	Positive	Positive	<b>Positive</b>	<b>Positive</b>	Positive
Batch 1	Togo	Bio-Rad Monolisa	Negative	Positive	Positive	<b>Positive</b>	Negative	Positive
Batch 1	Zimbabwe	Abbott Architect i2000	Negative	Positive	Positive	Negative	Negative	Positive
Batch 1	Mauritius	No response	<b>Positive</b>	Positive	Positive	<b>Positive</b>	<b>Positive</b>	Positive
Batch 1	Lesotho BTS	No Response	<b>Positive</b>	Positive	Positive	<b>Positive</b>	Negative	Positive
Batch 1	Gabon	No Response	Negative	Positive	Positive	Negative	Negative	Positive
Batch 1	Senegal	No response	Not tested	Not Tested	Not Tested	Not Tested	Not Tested	Not Tested
Batch 2	Uganda	No Response	Negative	Positive	Positive	<b>Positive</b>	<b>Positive</b>	Positive
Batch 1	Botswana NTC	No Response	Negative	Positive	Positive	Negative	Negative	Positive
Batch 1	Francistown-Botswana	No Response	<b>Positive</b>	Positive	Positive	<b>Positive</b>	Negative	Positive



Table 5: Participant Results and Method of Analysis (TPHA Panel 1)

TPHA	Participant	Method Of Analysis	VR-TP-01/22-A	VR-TP-01/22-B	VR-TP-01/22-C	VR-TP-01/22-D	VR-TP-01/22-E	VR-TP-01/22-F
VR01/22	<b>SANBS PT</b>	<b>Panther</b>	<b>Negative</b>	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>
	June Batch (SANBS)	Panther	Negative	Negative	Positive	Positive	Positive	Positive
	Batch 1 (SANBS)	Panther	Negative	Negative	Positive	Positive	Positive	Positive
	Batch 2 (SANBS)	Panther	Negative	Negative	Positive	Positive	Positive	Positive
	Batch 1 (Lancet)	Abbott Architect i2000	Negative	Negative	Positive	Positive	Positive	Positive
	Batch 2 (Lancet)	Abbott Architect i2000	Negative	Negative	Positive	Positive	Positive	Positive
	Room Temperature Batch 1	Panther PK7400	Negative	Negative	Positive	Positive	Positive	Positive
	Room Temperature Batch 2	Panther PK7400	Negative	Negative	Positive	Positive	Positive	Positive



Table 6: Participant Results and Method of Analysis (TPHA Panel 2)

TPHA	Participant	Method Of Analysis	VR-TP-02/22-A	VR-TP-02/22-B	VR-TP-02/22-C	VR-TP-02/22-D	VR-TP-02/22-E	VR-TP-02/22-F
VR02/22	<b>SANBS PT</b>	<b>Panther</b>	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	<b>Negative</b>	<b>Negative</b>	<b>Negative</b>
	June Batch (SANBS)	Panther	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	Negative	<b>Negative</b>	<b>Negative</b>
	Batch 1 (SANBS)	Panther	<b>Positive</b>	Positive	Positive	Negative	Negative	Negative
	Batch 2 (SANBS)	Panther	<b>Positive</b>	Positive	Positive	Negative	Negative	Negative
	Batch 1 (Lancet)	Abbott Architect i2000	<b>Positive</b>	Positive	Positive	Negative	Negative	Negative
	Batch 2 (Lancet)	Abbott Architect i2000	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative	Negative
	Room Temperature Batch 1	Panther PK7400	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative	Negative
	Room Temperature Batch 2	Panther PK7400	<b>Positive</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative	Negative
Batch 1	Lesotho	No response	Positive	Positive	Negative	Negative	Negative	Negative
Batch 1	Malawi	Abbott Architect	Positive	Positive	Negative	Negative	Negative	Negative
Batch 1	Namibia	Abbott Diagnostics	Positive	Positive	Negative	Negative	Negative	Negative
Batch 1	Mauritius	No Response	Positive	Positive	Negative	Negative	Negative	Negative
Batch 1	Botswana	No Response	Positive	Positive	Negative	Negative	Negative	Negative
Batch 1	Francistown - Botswana	No Response	Positive	Positive	Positive	Positive	Negative	Positive
Batch 1	Senegal	No Response	Positive	Positive	Negative	Negative	Negative	Negative
Batch 1	Togo	Bio-Rad Monolisa	Positive	Positive	Negative	Negative	Negative	Negative