





BIORAD GEENIUS HIV ½ CONFIRMATORY ASSAY

Bhekanani Shabalala

SAMRC-HPRU

19 Sep 17

MTN regional meeting

HOPE

HIV Open-label Prevention Extension
Out of ASPIRE, there is HOPE

sa**MRC**
advancinglife



INTRODUCTION

- Confirmatory assay for sero-converter participants.
- The Geenius HIV ½ Confirmatory Assay employs Ab binding protein A, which is conjugated to colloidal gold dye particles as conjugate.
- The sample is applied to the SAMPLE+BUFFER well. After the sample and buffer have migrated onto the test strip, additional buffer is then added to the buffer well.
- The buffer facilitates the lateral flow of released products and promotes the binding of antibodies to the antigens.
- In a reactive sample, the anti-HIV Ab's are captured by antigens immobilized in the test area.

CONTINUED.....

- Colloidal gold protein A binds to the captured Ab's, producing pink/purple lines in the test area.
- In the absence of HIV-Ab's, there is only a control line visible.

OVERVIEW

- General Geenius training
- Competency process
- Avoiding erroneous results, sample mix-ups and possible contamination.
- Review of results from CAP 2016 panel performed at the Chatsworth CRS.
- Troubleshooting
- Geenius Reader maintenance procedure

GEENIUS TRAINING

- Involves reading and fully understanding the HPRU's BioRad Geenius HIV ½ Confirmatory Assay S.O.P and Geenius user manual.
- S.O.P outlines:
 - i) Principle of the test
 - ii) Equipment/Materials and reagents required
 - iii) Test procedure e.g. IQC
 - iv) Sample type
 - v) EQA/Cap panels
 - vi) Testing device and Geenius Reader operating while testing
 - vii) Most importantly precautions related to the procedure

CONTINUED....

- Maintenance is then properly explained and demonstrated to the trainee.
- The training individual will then be asked questions regarding the test (Geenius), based on what they have learned from the S.O.P.
- The individual being trained will then be given an opportunity to observe, their trainer running the test, while adhering to the S.O.P.
- Should there be a sample available, the training individual will be observed processing the sample for competency purposes, ensuring that the S.O.P is adhered to.

CAP 2016 AHIV-B SAMPLE RAN

- CAP Rapid HIV (AHIV-B)-9
- CAP survey was received at HPRU on 15 Aug 16.
- Shipped to CRS site and performed at Chatsworth CRS on the 19 Aug 17.
- Survey was performed by a trained, Medical Technologist at the research site.

RESULTS

Survey name & Specimen number	Bothas Hill CRS	Chatsworth CRS	Isipingo CRS	Tongaat CRS	Verulem CRS
AHIV-B 06					
AHIV-B 07					
AHIV-B 08					
AHIV-B 09	Negative	Indeterminate (x2) Positive (x1)	Negative	Negative	Negative
AHIV-B 10					

Result images

Institution: South African Medical Research Council
Laboratory Director: Prof Gisa Ramjee
Service: MTN 225 Study

Address: Chabwath Clinical Research Site
Address2: RK Khan Clinic Chabwath
Country: RSA
City: KZN
ZipCode: 4030
Phone: +27314214160
Fax: +27314214563


Geenius HIV 1/2

Sample ID: AHIV-09
Cassette ID: 16A002314052
Kit Lot - Exp. Date: 6A0023 - 11/30/2017
Order date: 8/23/2016 10:30:36
Analysis date: 8/23/2016 10:30:36
Test run by: lab lab
Test version: 1.2-OLIS
Rule(s): HIV-2 Criteria - HIV-1 Criteria

Reader S/N: DP5K005107
Geenius version: 1.2.201.001
Last Calibration: 8/23/2016 08:53:47

Controls
Lot number: NC16C0023170315
Last run on: 8/23/2016 09:47:09
Lot number: PC16C0023170315
Last run on: 8/23/2016 09:47:54

Image



Interpretation
Interpretation type: Automatic

Band analysis:

#	Name	Result
1	gp36	Absent
2	gp140	Absent
3	p31	Absent
4	gp150	Absent
5	p24	Absent
6	gp41	Present
7	CTRL	Present

Conclusion: HIV-1 INDETERMINATE
Status: Validated by: lab lab

Print time: 4/4/2017 14:11:25 Printed with Geenius v1.2.201.001 Page 1 of 1

Institution: South African Medical Research Council
Laboratory Director: Prof Gisa Ramjee
Service: MTN 225 Study

Address: Chabwath Clinical Research Site
Address2: RK Khan Clinic Chabwath
Country: RSA
City: KZN
ZipCode: 4030
Phone: +27314214160
Fax: +27314214563


Geenius HIV 1/2

Sample ID: AHIV-09
Cassette ID: 16A002314047
Kit Lot - Exp. Date: 6A0023 - 11/30/2017
Order date: 8/23/2016 11:21:49
Analysis date: 8/23/2016 11:21:52
Test run by: lab lab
Test version: 1.2-OLIS
Rule(s): HIV-2 Criteria - HIV-1 Criteria

Reader S/N: DP5K005107
Geenius version: 1.2.201.001
Last Calibration: 8/23/2016 08:53:47

Controls
Lot number: NC16C0023170315
Last run on: 8/23/2016 09:47:09
Lot number: PC16C0023170315
Last run on: 8/23/2016 09:47:54

Image



Interpretation
Interpretation type: Automatic

Band analysis:

#	Name	Result
1	gp36	Absent
2	gp140	Absent
3	p31	Absent
4	gp150	Absent
5	p24	Absent
6	gp41	Present
7	CTRL	Present

Conclusion: HIV-1 INDETERMINATE
Status: Validated by: lab lab

Print time: 4/4/2017 14:12:20 Printed with Geenius v1.2.201.001 Page 1 of 1

Continued.....

Address1: Outsworld Clinical Research Site
Address2: Rik Khan Clinic Outsworld
 Country: RSA
 City: KZN
 ZipCode: 4030
 Phone: +27314214152
 Fax: +27314214363

Institution: South African Medical Research Council
Laboratory Director: Prof Gisa Kanger
Service: MTN Q23 Study

Genius HIV 1/2

Sample ID: AHV09
Cassette ID: 16A002314046
Kit Lot - Exp. Date: 6A0023 - 11/30/2017
Order date: 8/23/2016 11:55:38
Analysis date: 8/23/2016 11:55:31
Test run by: IHO QB
Test version: 1.2-OUS
Role(s): HIV-2 Criteria - HIV-1 Criteria

Reader S/N: DP9K055107
Genius version: 1.2.201.001
Last Calibration: 8/23/2016 08:53:47

Controls
 Lot number: NC16C0023170315
 Last run on: 8/23/2016 09:47:09
 Lot number: PC16C0023170315
 Last run on: 8/23/2016 09:47:54

Image


Interpretation
 Interpretation type: Automatic

Band analysis:

#	Name	Result
1	gp35	Absent
2	gp140	Absent
3	p21	Absent
4	gp160	Present
5	p24	Absent
6	gp41	Present
7	CTRL	Present

Conclusion: HIV-1 POSITIVE
 Status: Validated by: lab lab

Print time: 4/4/2017 14:20:16 Printed with Genius v1.2.201.001 Page 1 of 1

Address1: Outsworld Clinical Research Site
Address2: Rik Khan Clinic Outsworld
 Country: RSA
 City: KZN
 ZipCode: 4030
 Phone: +27314214152
 Fax: +27314214363

Institution: South African Medical Research Council
Laboratory Director: Prof Gisa Kanger
Service: MTN Q23 Study

Archive Summary

Sample ID	Cassette ID	Kit Lot - Exp. Date	Test name	Rule(s)	Order date	Analysis date	Status
AHV09	16A00231404	6A0023 - 11/30/2017 (1.2-OUS)	Genius HIV 1/2	HIV-2 Criteria - HIV-1 Criteria	8/23/2016 11:55:28	8/23/2016 11:55:31	Validated
Conclusion: HIV-1 POSITIVE							
AHV-09	16A00231404	6A0023 - 11/30/2017 (1.2-OUS)	Genius HIV 1/2	HIV-2 Criteria - HIV-1 Criteria	8/23/2016 11:21:49	8/23/2016 11:21:52	Validated
Conclusion: HIV-1 INDETERMINATE							
AHV-09	16A00231405	5A0023 - 11/30/2017 (1.2-OUS)	Genius HIV 1/2	HIV-2 Criteria - HIV-1 Criteria	8/23/2016 10:30:36	8/23/2016 10:30:38	Validated
Conclusion: HIV-1 INDETERMINATE							

Print time: 4/4/2017 14:19:49 Printed with Genius v1.2.201.001 Page 1 of 1

TROUBLESHOOTING

- Possible sample contamination was suspected by the Medical Technologist who ran the sample.
- In order to ascertain contamination, the sample 09 from Chatsworth was sent to Tongaat site. It appears that the tech from Chatsworth contaminated survey 09 sample with one of the positive samples in the panel.
- This was verified when Tongaat reran their sample and the result was positive.
- When Chatsworth site re-ran sample 09 obtained from another site, the result was negative, run by a different Medical Technologist.
- Weekly maintenance was completed prior to running the sample and the lens checked by the site. This is done when the control is run weekly.

INNER SURFACE/LENS CLEANING

- The inside of the cassette-loading compartment is protected by a flap and does not normally require any periodic cleaning.
- It is nevertheless recommended that you check regularly (e.g. once a week).
- That the inner surface of the image capture zone is free of stains or any foreign matter that could have entered the cassette loading compartment.

Procedure

Real-time view:



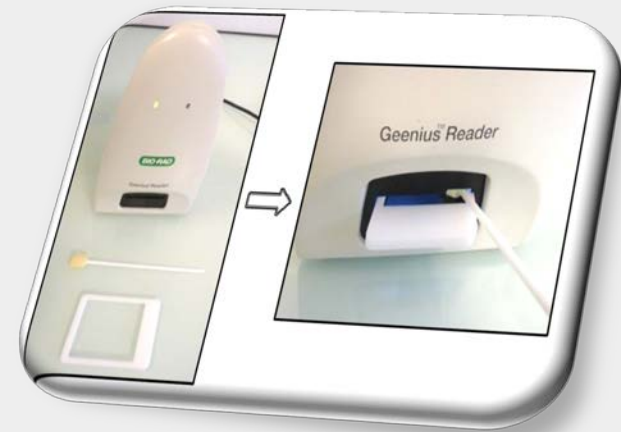
- 1. Click the Instrument button in the toolbar to open the Instrument window.
- 2. In the Instrument window, select the **Maintenance tab**. On the right-hand side of this tab, a small “Live window” provides a real-time view of the surface of the image capture zone.
- 3. Make sure this surface is clean and free of stains and foreign matter. If it is not, clean as described below.
- 4. In addition to this visual check, the system performs an automated verification of this area during the calibration process.

READER MAINTENANCE

- For this cleaning procedure, you need the maintenance kit provided with the Geenius™ Reader.
- The maintenance kit includes:
 - 1) a foam swab
 - 2) and a rectangular plastic frame.

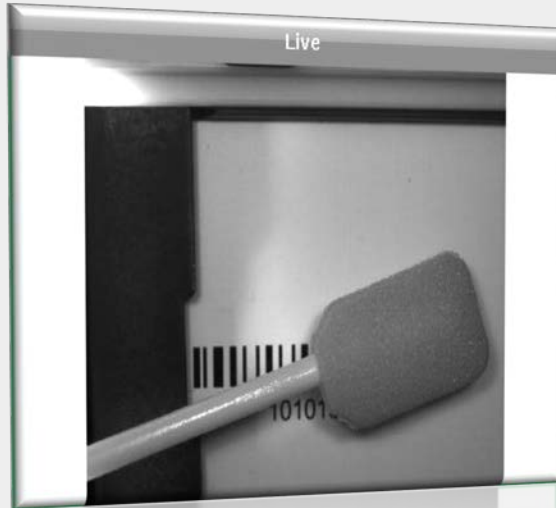
Procedure.....

- 1. Make sure the Geenius™ Reader is connected to the computer and that the Live view of the image capture zone (Instrument window, Maintenance tab) is displayed
- 2. Insert the plastic frame in the Geenius™ Reader.
- 3. Insert the foam swab on the right-hand side where the opening is slightly wider.



Continued.....

4.



- 4. Through the live view window, you can now see the foam swab inside the Geenius™ Reader.
- 5. Move the swab around to clean (be careful not to push dirt further inside the compartment or underneath the flap!).
- 6. When done, remove the swab and the plastic frame.
- Note: Perform this procedure preferably with a dry foam swab. If necessary (e.g. hard stain), you can moisten the swab slightly with deionised water. In this case, allow to dry.

OUTCOME- FINAL CONCLUSION

- An Investigation Report (IR) was submitted to SMILE.
- A revised IR (original IR dated November 3rd, 2016) sent by Wayne Hall MT (ASCP) for MTN, concluded further investigations were recommended by SMILE.
- This investigation then led to the conclusion that the technologist from Chatsworth may have contaminated survey 09 sample with one of the positive samples (most likely from the sample before 09 which was positive).
- Preventative measures will be investigated further if this becomes an escalated problem in the future.
- Refer to Appendix A.



ACKNOWLEDGEMENTS

- **Wayne Hall**
- **Ted Livant**
- **Rashika Maharaj (Laboratory manager)**
- **Laboratory team**

THANK YOU !!!!!

