



Comparison of Dried Tube and Plasma Specimens in an External Quality Assessment Scheme and Evaluation of Quality of HIV Rapid Testing Performed by Non-Laboratory Staff in Lesotho.

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Background: Demographics

- Population: 1,880,661 in 10 districts
- Adult HIV prevalence: 23.2%

(above figures taken from Lesotho MoHSW Annual Joint Review Report 2007/08)

- By 2008: 55,512 adults on ART
4,446 children on ART

(above figures taken from Lesotho MoHSW Annual Joint Review Report 2008/09)

Background: Testing Services

- Services decentralized throughout 10 districts
- Laboratory national strategic and operational plan, and policy developed 2009
- HIV Rapid Testing (RT) plan developed 2009, including EQA implementation plan
- HIV rapid testing conducted by non-laboratory personnel at health centers, hospital clinics and community settings
- HIV rapid testing is done at 21 hospitals, 184 health centers & by Community Based Care Givers
- It is critical to implement, monitor and evaluate testers/facilities to assure quality test results

DTS/Plasma proficiency panel for HIV Rapid Testing: a comparison study

1: Introduction

2: Materials and Methods

3: Results

4: Conclusion

1. Introduction

- Traditionally plasma specimens used for PPT as part of External Quality Assessment Scheme (EQAS)
- Plasma panels:
 - Require large volumes of plasma material
 - Important to maintain integrity of plasma specimens via the cold chain
 - Relatively short stability at ambient temperatures
- Hence, an alternative method, the Dried Tube Specimen (DTS) was developed and introduced by CDC-ILB Atlanta
- Plasma/DTS PPT evaluated in Mafeteng district by the Quality Assurance Unit (QAU) Lesotho Laboratory Services, MOHSW, 2009

2. Materials and Methods

- Paired plasma and DTS proficiency panels were made by the Quality Assurance Unit (QAU), Lesotho Laboratory Services, MOHSW in accordance with CDC-ILB SOP
- DTS reagents and materials supplied by CDC-ILB
- Plasma was obtained from Lesotho Blood Transfusion Services
- 139 non-laboratory testers from 15 health centers, clinics, hospital testing points and NGOs at Mafeteng district tested the paired plasma and DTS PPT specimens
- Six specimens including positive and negative specimens in each panel

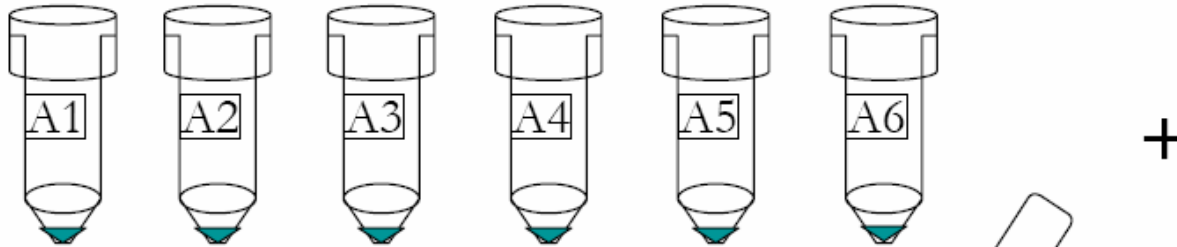
Materials and Methods Cont.

- Site supervisors were trained in EQAS by QAU, who then trained testers on-site
- All specimens tested in accordance with the national serial testing algorithm (Determine, Double Check, Bioline)
- Standardized result and report forms provided in Sesotho language
- Result reports from the testing sites were submitted to the QAU for analysis and timely report feedback provided to the sites by QAU

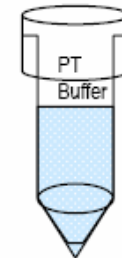
DTS Testing Instructions

Six PT specimens (A1 to A6)

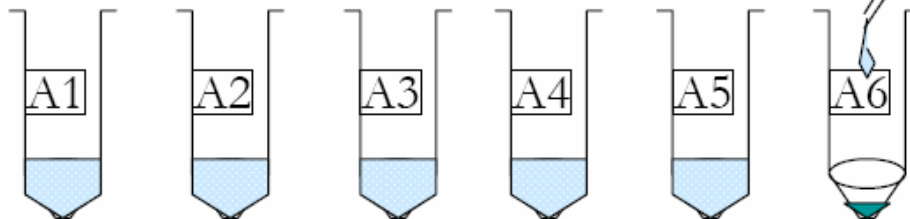
(ensure green pellet is at the bottom of the tube)



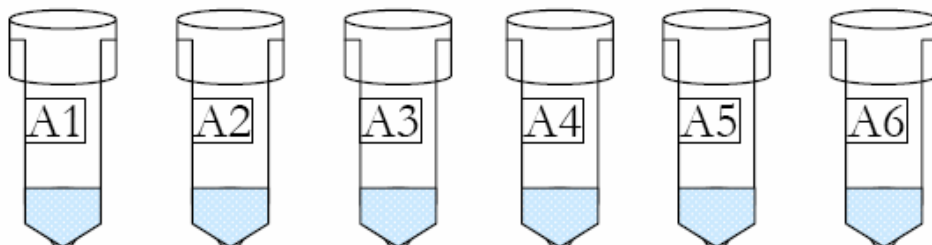
1 vial of PT buffer



**Add exactly 7 drops of
PT Buffer to each tube**



**Cap the tubes, tap few times to mix well and
Incubate at room temperature overnight**



**Next day, tap to mix the
contents and perform R
as per algorithm**

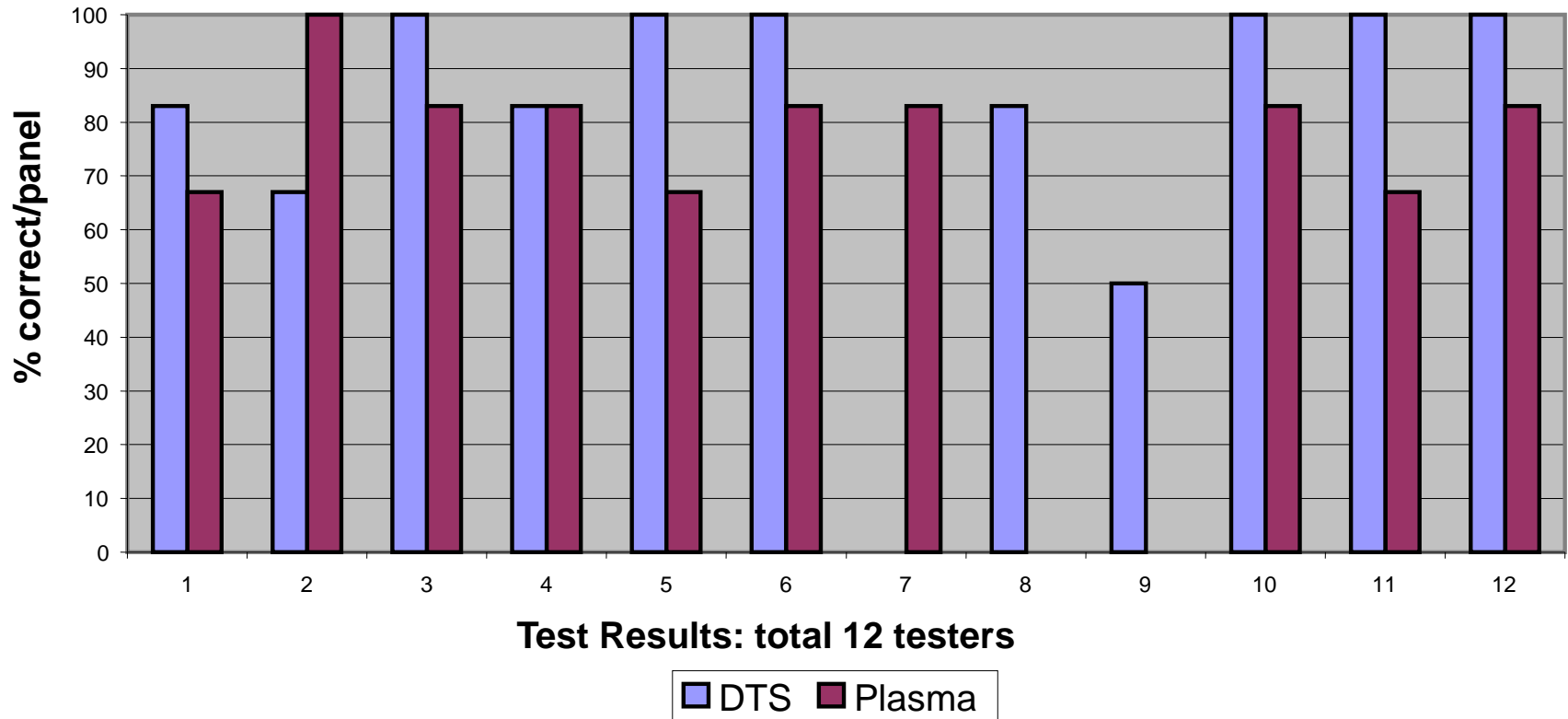
3. Results 1. DTS and/or Plasma

- For unknown reasons testers at a few sites tested either DTS or plasma panels, but not both, hence the total number of testers who tested both plasma and DTS panels vary in numbers and are shown below.
- Total testers of DTS and/or plasma panels = 139
- 121 / 126 (96%) scored 100% for DTS panels
- 120 / 129 (93%) scored 100% for plasma panels

3. Results 1. DTS and/or Plasma cont.

- 12/139 (7%) scored < 100% correct (6/6) for plasma or DTS panels
- Of the 12 testers with <100% correct for DTS or plasma
one site accounted for 6 (half) of all testers that did not score 100%
- 5/15 sites had one or more testers that did not score 100%
- All sites received follow up to review individual results, overall study results and corrective actions as needed, e.g., additional training

All testers <100% (6/6) correct (DTS or plasma)



Summary of testers scoring 100% by site and by specimen type (plasma and DTS specimens)

Mafeteng Facility Code	No.testers/ DTS 100% correct (6/6)	No. testers plasma 100% correct (6/6)
1	17/17	17/17
2	9/9	5/7
3	24/27	20/25
4	15/15	15/15
5	6/8	1/1
6	17/17	15/16
7	DTS not tested	9/10
8	1/1	1/1
9	11/11	12/12
10	6/6	6/6
11	6/6	6/6
12	1/1	1/1
13	1/1	1/1
14	1/1	1/1
15	1/1	1/1
	121/126	120/129
	96%	93%

Incorrect results per Plasma (P) and DTS (D) specimens

Specimen number	Total correct plasma (n= 129)	Total correct DTS (n=126)
P1 or D1	129	125
P2 or D2	129	125
P3 or D3	126	126
P4 or D4	128	123
P5 or D5	127	125
P6 or D6	123	124

Results 2. DTS : Plasma Correlation

- Total DTS and plasma panel pairs tested = 116
- DTS panel:
 - 113/116 (97%) testers scored 100% (6/6)
 - 3 testers scored <100% (83%, 67%, 83%)
- Plasma panels:
 - 108/116 (93%) testers scored 100%
 - 8 testers scored <100%

(67%, 83%, 83%, 67%, 83%, 83%, 67%, 83%)
- 97% DTS correct vs. 93% plasma correct

4. Conclusion

- Results were 4% higher for DTS than plasma panels (97% vs. 93%)
- DTS is more stable than plasma and requires less plasma for making panels
- DTS will be employed for PPT as part of EQA and for QC for rapid testing at all non-laboratory testing facilities in Lesotho
- Important to follow up testers/sites <100% correct via competency assessment, supervision and refresher training
- Although PPT participation for HIV RT by all testers is expensive, it is critical to assure quality HIV RT results are provided to each client tested

References

1. Lesotho Laboratory Strategic Plan, MOHSW, 2009
2. Lesotho Laboratory Operational Plan, MOHSW, 2009
3. Lesotho Laboratory Quality Assurance Plan for HIV Rapid Testing, MOHSW, 2009
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6. Dried tube specimens: A simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings. Bharat S. Parekh, Juliana Anyanwu, Hetal Patel, Marie Downer et al; ILB-CDC, Atlanta. Journal of Virological Methods, Volume 163, Issue 2, February 2010, Pages 295-300