

A case of collection tubes causing hemolysis on Coagulation Samples

By Edwin Shumba
UZ-UCSF Lab QA/QC Scientist



University of Zimbabwe
College Of Health Sciences

UZ - UCSF
Collaborative Research Programme

15 Phillips Avenue, Belgravia, Harere, Zimbabwe,
Telephone: +263 4 704890/704920/722620 Fax: +263 4 704897/725038



University of California,
San Francisco,
School of Medicine

Introduction

- Total quality in Clinical lab testing is a necessary requisite to achieve clinically reliable results
- There is a high prevalence of pre-analytical problems affecting samples for coagulation testing.
- Hemolysis is one the leading source of unsuitable specimens for routine coagulation testing

CASE

- Received 3 samples on the same day (1Apr 08) from one clinic all were hemolyzed.
- Collected by different nurses.
- Tubes used were from a different manufacturer.
- Routinely we were using tubes BD Vacutainer 2.7ml tubes 3.2% citrate

CASE

- Manufacturer : **VACUCARE**
- Citrate concentration- **Not indicated**
- Expiry date -June 2008
- These were causing hemolysis.



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Case- Continued

- Based on *WHO recommendations and NCCLS guidelines*, 3.2% citrate is the anticoagulant of choice for coagulation testing.

- *Arch Pathol Lab Med. 1998;122:768-781*

Troubleshooting

- During troubleshooting the following were looked at:
 - ✓ specimen collection or handling,
 - ✓ mixing of the blood after collection,
 - ✓ exposure to excessively hot or cold temperature
 - ✓ centrifugation speeds and time



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Troubleshooting

- ✓ Expiry dates
- ✓ Staff competence
- ✓ All these were found to be **OKAY**



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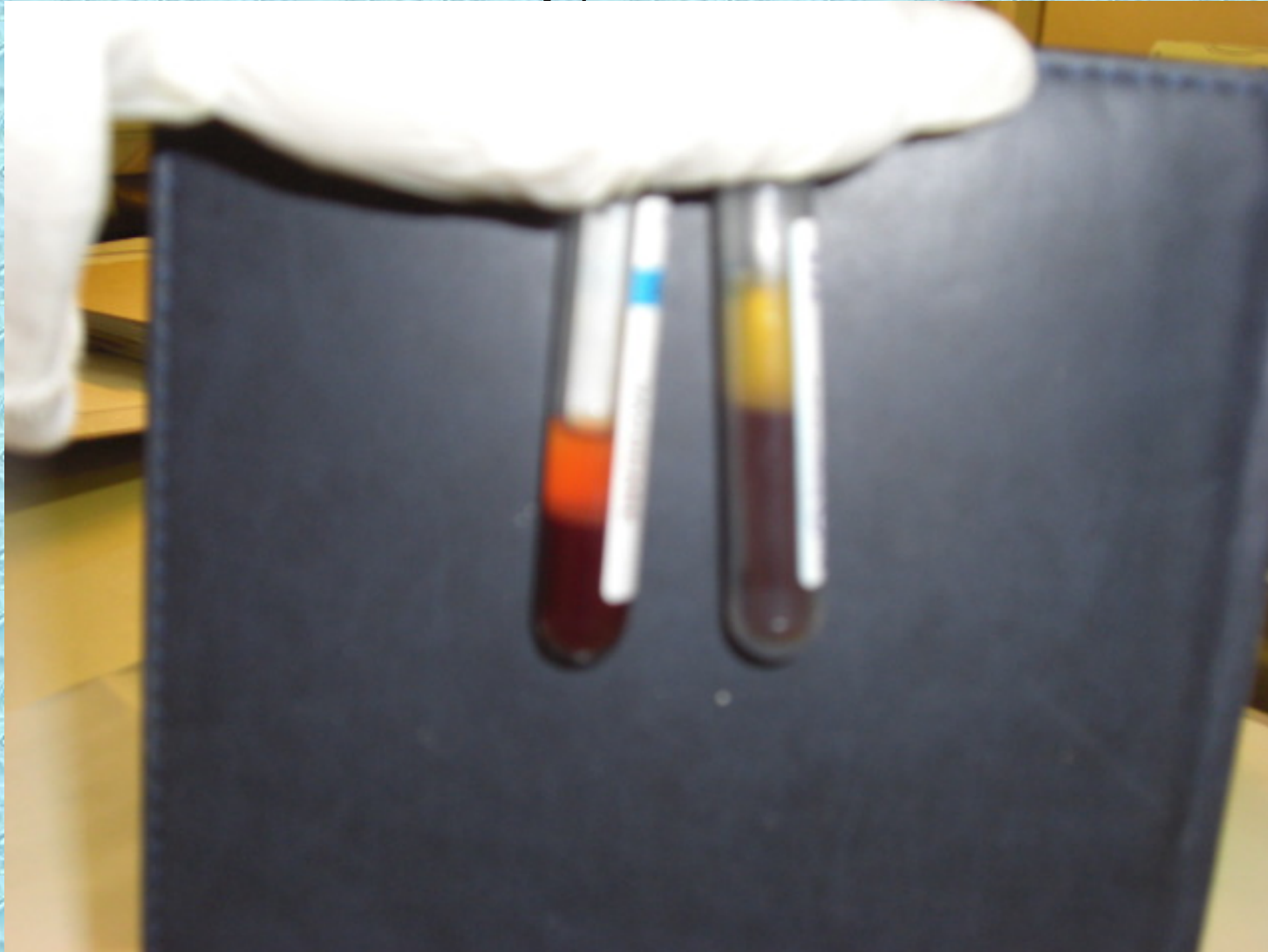
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Investigation-Photos





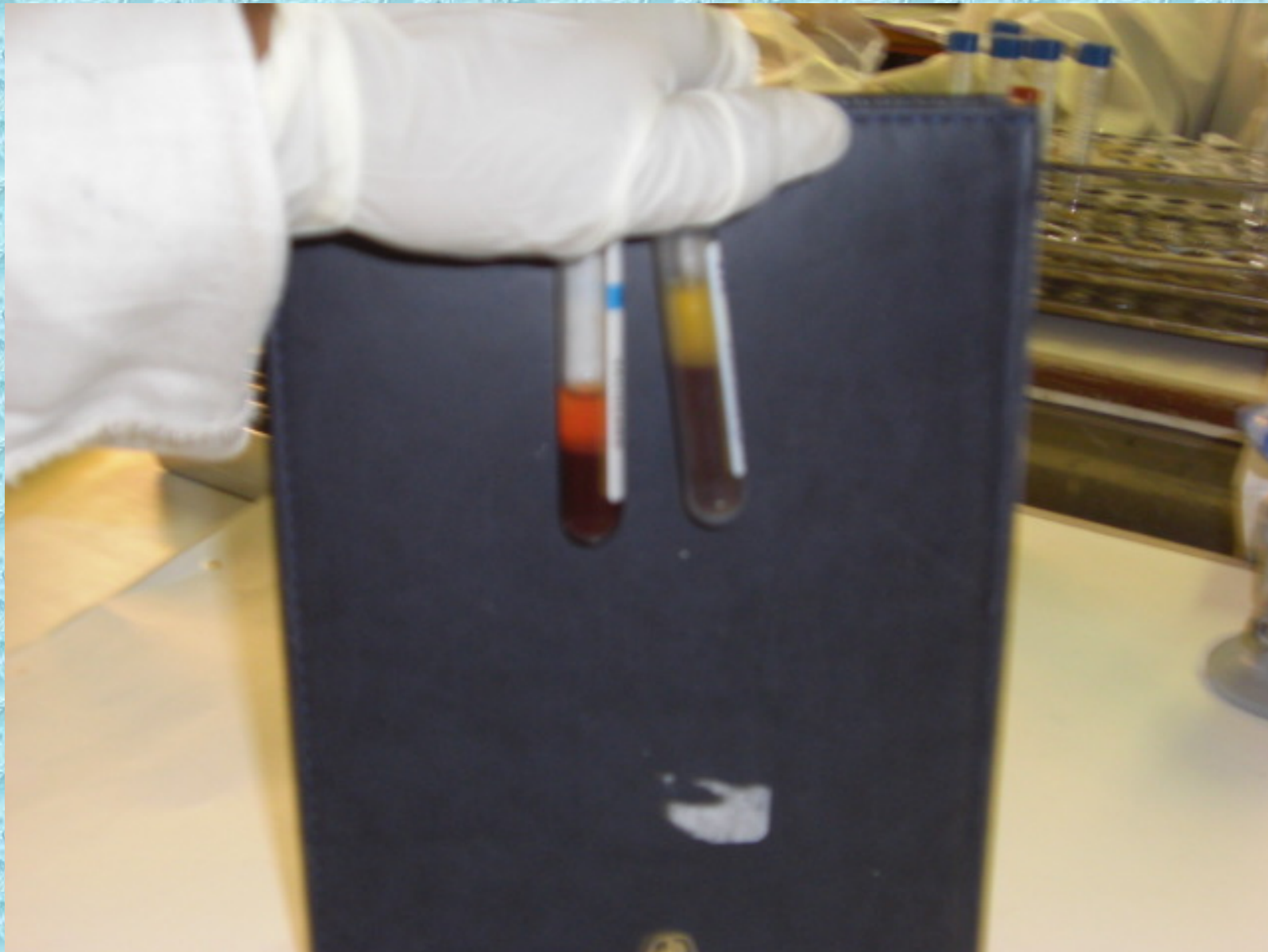
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Investigation cont

	BD Vacutainer	Vacu Care Vacuum tube
Citrate concentration	3.20%	Not Known
Anticoag Type	liquid	sprayed
Volume	2.7ml	2.7ml
Sample quality	OK	hemolyzed ¹⁰



Comparison of the Results

		BD Vacutainer	Vacucare Vacuum tube
PPT 1	PT	14.4s	14.6s
	APTT	47.5s	55.0s
PPT 2	PT	13.1s	13.4s
	APTT	57.8s	61.8s
PPT 3	PT	12.0s	12.1s
	APTT	30.4s	54.6s



CASE Corrective action

The tubes from **VacuCare** were causing hemolysis probably due to :

1. Anticoagulant ratio NOT known.. ??
2. Manufacturing defect??

We therefore stopped using the **VacuCare tubes, asked for redraws and the whole problem was resolved**



Analysis of results

- In this case Hemolyzed patient specimens exhibited significant differences in activated partial thromboplastin time (APTT), compared to non-hemolyzed specimens



Conclusion

- Compliance with a Quality Management System (QMS), encompasses the adoption of suitable strategies for reducing undue variability throughout the testing process.
- Our QMS is based on the ISO 15189 standard
- Hence all this investigation and subsequent Corrective action



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- Quality requires effort and the benefits of quality make the effort worthwhile

- Thank You