

Determination of Root Causes of Non-conformities

Characters/ Activities Evaluated	Cause/ Error Identified			
	Yes	No	Responsibility	Comments
II. PRE-SURVEY ISSUES				
1). The EQA provider distributed by accident an inappropriate sample		✓	EQAP	
2). Error in sample labelling		✓	EQAP	
3). Error in packing the sample		✓	EQAP	
4). Error in distribution of sample		✓	EQAP	
5). Problem with sample stability		✓	EQAP	
6). Problem with sample homogeneity		✓	EQAP	
7). Error in instruction letter of EQA provider		✓	EQAP	

Description of the Cause

Corrective action proposed

Prepared by QM *MJL* Reviewed & Approved TD *[Signature]* Issued MD *[Signature]*

MICROBIOLOGICAL LABORATORY		DEPARTMENT OF QUALITY MANAGEMENT		
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IV. TEST PERFORMANCE				
1). Change in the instruction of manufacturer		✓	Participants/ EQAP/ Manufacturer	
2). Was there a problem with the equipments		✓	Participants	
3). Was there a problem with reagents		✓	Participants/ Manufacturer	
4). Was there a problem with the test performance		✓	Participants	
5). Was there a problem with the IQC samples		✓	Participants	
Description of the Cause				
Corrective action proposed				
Prepared by QM <i>M. J. ...</i>		Reviewed & Approved TD <i>[Signature]</i>		Issued MD <i>[Signature]</i>

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VI. REPORT AND INTERPREATION				
1). Deviation in accordance with previous EQA results		✓	Participant/ EQAP/ Manufacturer	
2). Large variation in EQA results for the method used		✓	EQAP/ Manufacturer	
3). Deviation in systematic for all EQA samples		✓	Participant/ EQAP/ Manufacturer	
4). Repeated analysis showed similar deviation		✓	Participant/ EQAP/ Manufacturer	
5). Source of deviation is unknown	✓	✓	Participant/ EQAP/ Manufacturer	
Description of the Cause				

Since IQC values are within the range and machine maintenance performed perfectly, the source of deviation is unknown, hence corrective action proposed we considered as random error.

M. S. ...

Prepared by QM <i>M. S. ...</i>	Reviewed & Approved TD <i>(Signature)</i>	Issued MD <i>(Signature)</i>
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