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Root Ca	uses of	Non-c				
	Cause/ Error Identified					
	Yes	No	Responsibility	Comments		
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	Determination of Ro	ot Causes	of	Non-co	nformities		
Characters/ Activities Evaluated		Cause/ Error Identified					
		Ye	 s	No	Responsibility	Comments	
II. PRI	E-SURVEY ISSUES						
). The EQA provider of the properties of the EQA provider of the E	listributed by accident an			~	EQAP		
). Error in sample lab				✓	EQAP		
s). Error in packing th	e sample			/	EQAP	8	
4). Error in distributio	on of sample			/	EQAP		
5). Problem with san	ple stability			~	EQAP		
6). Problem with san	nple homogenicity			1/	EQAP	-	
7). Error in instructio	n letter of EQA provider			1	EQAP		
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Description of t	he Cause						
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Corrective action	on proposed						
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Characters/ Activities Evaluated			Cause/ Error Identified				
			Yes	No	Responsibility	Comments	
III.SAMPLE	RECEIPT/ HANDLING			V			
1). Problem with the sa	mple receipt			\checkmark	Participants		
2). Inappropriate storag	ge of the sample till use			V	Participants		
3). Problem with recon	stitution of the sample			/	Participants		
 The instructions we participants 	re not followed properly by	y the			Participants		
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Description of the	Cause						
Corrective action p							
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Characters/ Activities Evaluated		Cause/ Error Identified					
			Yes	No	Responsibility	Comments	
IV. TES	T PERFORMANCE						
1). Change in the instru	action of manufacturer			✓	Participants/ EQAP/ Manufacturer		
2). Was there a problem	m with the equipments			\checkmark	Participants		
3). Was there a proble	m with reagents			\checkmark	Participants/ Manufacturer		
4). Was there a proble	m with the test performan	nce		1	Participants		
5). Was there a proble	em with the IQC samples			V	Participants		
Description of the	e Cause						
Corrective action	proposed						
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Determination of Root Causes of Non-conformities							
Characters/ Activities Evaluated		Cause/ Error Identified					
and deterny metrices available		Yes	No	Responsibility	Comments		
V. DATA HANDLING EQA PROVIDE	R						
t). The ststistical procedure used is probably not appropriate for the distribution of test			~	EQAP			
2). Error establishment of assigned value (AV)			1/	EQAP			
3). Error in presentation of results			/	EQAP			
Description of the Cause							
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Corrective action proposed							
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DEPARTMENT OF QUALITY MANAGEMENT MICROBIOLOGICAL LABORATORY P 1/10 F/MBL/TVL/QMD/RCA/NC 01-01-2020 **VERSION 1.0 Determination of Root Causes of Non-conformities** Cause/ Error Identified **Characters/ Activities Evaluated** Comments Responsibility Yes VI. REPORT AND INTERPREATION Participant/ EQAP/ 1). Deviation in accordance with previous EQA results Manufacturer EQAP/ 2). Large variation in EQA results for the method used Manufacturer Participant/ EQAP/ 3). Deviation in systematic for all EQA samples Manufacturer Participant/ EQAP/ Repeated analysis showed similar deviation Manufacturer Participant/ EQAP/ 5). Source of deviation is unknown Manufacturer Description of the Cause since ige volues are within the stonge end matthe maintenace performed pertectly, its source of dewichen is unknow, here Corrective action proposed we considered as andom error. Preoared by QM Million 1771 Reviewed & Approved TD Issued MD