Scenario 1: The case of who's reactive, and who's not?

Materials

Remel RPR Card method Package Insert (Macro-Vue, Randox, & Remel RPR kits are very similar, and are based on the same concept).

RPR worksheet?

- Part 1: Read & complete before going to Part 2 or 3. DO NOT change your answers after moving on to part 2 or part 3

Background: Lab located in central Gaborone, Botswana in mid-September (dry, hot season).

Jim, a new quality assurance technician and recently appointed to this position, was reviewing the serology testing log for the Remel RPR card method and noticed that there were 4 reactive RPR's in the past week (out of 10 that were run). He noticed that 3 (samples A, F, & J) of the confirmation tests were negative. The three positive RPR's only had the undiluted sample that showed reactivity. He investigated further, and did not find any quality control failures noted on recent logs.

Is Jim done, or should he investigate further?

LC: Investigate further

1. Needs to investigate why there were so many reactive RPR's in a short period of time that disappeared with the first dilution.
2. Very high coincidence that all three of these have a neg confirmation test.
   -maybe due to false positives from interfering substances, previous infection that was treated, other?

What may be your next step?

LC:

- Look farther back in the log to see if this is reoccurring over a longer time.
- Look at past EQA results
- Repeat samples A,F, & J

• Sample Details			**For Part 1**			
PTID	Visit Code	Sample Date	RPR	**RPR Titer***	**TPHA**	**Comments**
A	27	4-Aug-12	POSITIVE	1:1	Neg	
B	23.0	12- Aug-11	NEGATIVE	N/A		
C	21	26- Aug-11	NEGATIVE	N/A		
D	15.0	5- Aug-12	NEGATIVE	N/A		
E	9	21- Aug-11	NEGATIVE	N/A		
F	17.0	24- Aug-11	POSITIVE	1:1	Neg	
G	18	28- Aug-11	NEGATIVE	N/A		
H	3	4- Aug-10	NEGATIVE	N/A		
I	9.0	26- Aug-11	POSITIVE	1:8	Pos	
J	30.0	21- Aug-12	POSITIVE	1:1	Neg	

Note: All runs had QC performed and were in limits

Go to Part B….

Part 2

Jim looked back at previous EQA, and noted that they missed 2 out of 5 on a CAP panel run about 2 months ago. One of the samples was a false positive and the other had higher dilution reactivity than the consensus group.

Jim had the lab technologist pull out the 3 samples (A, F, & J) that were reactive and repeat them on the next RPR testing. A total of 10 specimens were run.

The technologist saw that 2 of the original samples (F & J) were non-reactive, 1 of the original samples (A) was still reactive at a 1:1 dilution, and a new sample (Q) became reactive at 1:1 dilution.

The RPR on the Sample Q RPR was repeated and came out reactive at 1: 2, but the confirmation test (TP-PA) was negative.

What do you think the problem is?

LC: If this is repeat pattern for the past few months, then something is wrong with the test, test procedure, or technique.

What is the next step?

LC: Look at package insert to see if test is being conducted correctly, storage requirements are being met, all QC such as speed/timing of rotor and drop count.

Sample Details			**Part 2**				
PTID	Visit Code	Sample Date	RPR	**RPR Titer***	**TPHA**	**Repeat RPR& titer**	
A	27	4-Aug-12	POSITIVE	1:1			
F	17	24- Aug-11	NEGATIVE				
J	30	21- Aug-12	NEGATIVE				
K	15	5- Aug-12	NEGATIVE	N/A			
L	9	21- Aug-11	NEGATIVE	N/A			
M	17	28- Aug-11	NEGATIVE	N/A			
N	18	28- Aug-11	NEGATIVE	N/A			
O	3	4- Aug-10	NEGATIVE	N/A			
P	9	26- Aug-11	POSITIVE	N/A			
Q	20	21- Aug-12	POSITIVE	1:1	Neg	Pos @ 1:2	

Note: All runs had QC performed and were in limits

Part 3

While driving into work the next day, as the rain pitter-patted on to his wind shield, he thought that this may be a 'bad' lot issue, and instituted a new RPR lot to be run. Also, Jim wanted to watch the technologist perform the run on some new samples and the repeat samples A, F, J, & Q that were initially reactive, but confirmation test negative.

These were the steps followed:

The tech removed the new kit from the refrigerator, and started the QC process as the kits warmed up to room temperature. He checked the expiration date of the kit, removed one card from the plastic bag and placed on the rotator, performed a mechanical rotator check (using a pencil & NIST calibrated timer), checked the needle for correct drop size (using syringe fill with .5ml of suspension & counting the drops) & wiped it when finished with gauze, and moved a good light source near rotator so reactions could easily be seen.

After labeling all cards & log sheet, the samples were correctly dropped & flattened out using the kits stirrers. The antigen bottle was shaken and a drop of suspension was placed in the center of each well. The rotator was set for 8 minutes. Following rotation the card was picked up and slowly rotated 3-4 times to check for clumping. Of the 10 samples, the positive control and sample W was reactive at a 1:1 dilution, all other samples were non-reactive.

Was the 'new lot' the resolution to the false positives that Jim was seeing on the previous logs and previous EQA?

LC: No, this is not a lot issue

If not, what can you identify?

LC:

1. There was no humidity cover used. The wells were drying out, and this can then appear to look like clumping.
2. During the drop test, the dispensing bottle needle was wiped. This practice can affect the dispensing properties of this needle. The needle should be rinsed with distilled or deionized water and air dried.

EQA Failures: most likely, these were the result of the same situation (drying out wells).

Sample Details			**Part 3**		
PTID	Visit Code	Sample Date	RPR	**RPR Titer***	**TPHA**
A	27	4-Aug-12	NEGATIVE		
F	17	24- Aug-11	NEGATIVE		
J	30	21- Aug-12	NEGATIVE		
Q	15	5- Aug-12	NEGATIVE		
R	9	21- Aug-11	NEGATIVE		
S	17	28- Aug-11	NEGATIVE		
T	18	28- Aug-11	NEGATIVE		
U	3	4- Aug-10	NEGATIVE		
V	9	26- Aug-11	NEGATIVE		
W	20	21- Aug-12	POSITIVE	1:1	Neg