

Date Issued: 22nd Nov 22**Complaint Reference:** REC629**Action Type:** Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch/ Lot number	Expiry Date	Manufacturing Date
Liquid Assayed Specific Protein Control Level 1	PS2682	05055273204896	584LPC	28 th Jun 23	4 th Nov 2020
			600LPC	28 th Nov 23	14 th Apr 22
			611LPC	28 th Sep 24	7 th Apr 22
			615LPC	28 th Nov 22	8 th Oct 21
			636LPC	28 th Jan 23	7 th Dec 21
			638LPC	28 th Jan 24	12 th Apr 22
Specific Protein Control Level 1	PS10221	05055273215670	600LPC	28 th Nov 23	16 th Jun 21
			611LPC	28 th Sep 24	23 rd May 22
Liquid Assayed Specific Protein Control Level 2	PS2683	05055273204902	585LPC	28 th Jun 23	6 th Nov 2020
			601LPC	28 th Nov 23	7 th Oct 21
			612LPC	28 th Sep 24	27 th Jan 22
			616LPC	28 th Nov 22	21 st May 21
			634LPC	28 th Sep 23	28 th Jan 22
			639LPC	28 th Jan 24	12 th Apr 22

Specific Protein Control Level 2	PS10222	05055273215687	601LPC	28 th Nov 23	6 th Sep 21
			612LPC	28 th Sep 24	7 th Dec 21
Liquid Assayed Specific Protein Control Level 3	PS2684	05055273204919	586LPC	28 th Jun 23	4 th Nov 2020
			602LPC	28 th Nov 23	4 th Jul 22
			628LPC	28 th Dec 24	26 th May 22
			635LPC	28 th Sep 23	29 th Nov 21
			640LPC	28 th Jan 24	26 th May 22
Specific Protein Control Level 3	PS10223	05055273215694	586LPC	28 th Jun 23	16 th Jun 21
			602LPC	28 th Nov 23	7 th Sep 21

Reason for Action:

The concentration of Rheumatoid Factor (RF) has decreased in Radox Specific Protein Controls Levels 1-3. Affected catalogue and lot numbers are listed above.

Table 1: QC Level 1-3 Target value average % Change

Analyte	QC Level	Average % Change
Rheumatoid Factor (RF)	Level 1	-24%
Rheumatoid Factor (RF)	Level 2	-16%
Rheumatoid Factor (RF)	Level 3	-14%

The tables below detail the reassigned targets and ranges for each of the affected lot numbers for Rheumatoid Factor Non IFCC Turbidimetric and Siemens Nephelometric methods.

Table 2: Specific Protein Control Level 1 (PS2682 and PS10221)

Catalogue Number	Lot Number	(Non IFCC) Turbidimetric Method				Siemens Nephelometric Method			
		Old Target Value	Old Range	New Target Value	New Range	Old Target Value	Old Range	New Target Value	New Range
PS2682/ PS10221	600LPC	16.2	13.0-19.4	12.4	9.30-15.5	15.8	12.6-19.0	12.4	9.30-15.5
	611LPC	20.6	16.5-24.7	15.9	11.9-19.9	20.8	16.6-25.0	15.9	11.9-19.9
PS2682	584LPC	17.1	13.7-20.5	12.7	9.53-15.9	17.4	13.9-20.9	12.4	9.30-15.5
	615LPC	16.2	13.0-19.4	12.4	9.30-15.5	15.8	12.6-19.0	12.4	9.30-15.5
	636LPC	16.2	13.0-19.4	12.4	9.30-15.5	15.8	12.6-19.0	12.4	9.30-15.5
	638LPC	20.6	16.5-24.7	15.9	11.9-19.9	20.8	16.6-25.0	15.9	11.9-19.9

Table 3: Specific Protein Control Level 2 (PS2683 and PS10222)

Catalogue Number	Lot Number	(Non IFCC) Turbidimetric Method				Siemens Nephelometric Method			
		Old Target Value	Old Range	New Target Value	New Range	Old Target Value	Old Range	New Target Value	New Range
PS2683/ PS10222	601LPC	36.1	28.9-43.3	30.9	23.2-38.6	32.0	25.6-38.4	27.1	20.3-33.9
	612LPC	39.8	31.8-47.8	34.8	26.1-43.5	37.7	30.2-45.2	30.3	22.7-37.9
PS2683	585LPC	35.8	28.6-43.0	29.5	22.1-36.9	33.8	27.0-40.6	26.2	19.7-32.8
	616LPC	36.1	28.9-43.3	30.9	23.2-38.6	32.0	25.6-38.4	27.1	20.3-33.9
	634LPC	39.8	31.8-47.8	34.8	26.1-43.5	37.7	30.2-45.2	30.3	22.7-37.9
	639LPC	39.8	31.8-47.8	34.8	26.1-43.5	37.7	30.2-45.2	30.3	22.7-37.9

Table 4: Specific Protein Control Level 3 (PS2684 and PS10223)

Catalogue Number	Lot Number	(Non IFCC) Turbidimetric Method				Siemens Nephelometric Method			
		Old Target Value	Old Range	New Target Value	New Range	Old Target Value	Old Range	New Target Value	New Range
PS2684/ PS10223	586LPC	54.1	43.3-64.9	46.2	34.7-57.8	50.4	40.3-60.5	39.2	29.4-49.0
	602LPC	54.8	43.8-65.8	48.5	36.4-60.6	45.2	36.2-54.2	38.4	28.8-48.0
PS2684	628LPC	54.2	43.4-65.0	51.0	38.3-63.8	42.5	34.0-51.0	35.0	26.3-43.8
	635LPC	58.4	46.7-70.1	54.6	41.0-68.3	53.3	42.6-64.0	42.5	31.9-53.1
	640LPC	54.2	43.4-65.0	51.0	38.3-63.8	42.5	34.0-51.0	35.0	26.3-43.8

Risk to Health:

Rheumatoid Factor (RF) is a protein whose levels are increased in patients with Rheumatoid Arthritis. Delay in reporting results due to Quality Controls running low outside range, leading to a negligible risk to patients.

Action to be taken:

- Discard previous IFUs and download the updated IFUs from radox.com
- Review results generated with the affected batches in line with the clinical profile of the patient.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@radox.com within five working days.

Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns, please contact Radox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency