CONFIDENTIAL

Date: 21st Nov 22

Recall number: REC629
R.A. Reference number: TBD

Name	Address	Product received	Date Received
Siemens Germany	European Distribution Centre, Antwerpener Strasse 1, 47229 Duisburg-Rheinhausen, Germany	PS2682 x 1	10 Mar 21
Bayer AG Elberfeld Technik	Friedrich Ebert Strasse, D-42117, Wuppertal Elberfeld, Germany	PS2682 x 1 PS2683 x 1	19 Jul 22

RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

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	28th Jun 23	4th Nov 2020
			600LPC	28th Nov 23	14th Apr 22
			611LPC	28th Sep 24	7th Apr 22
			615LPC	28th Nov 22	8th Oct 21
			636LPC	28th Jan 23	7th Dec 21
			638LPC	28th Jan 24	12th Apr 22
Specific Protein Control Level 1	PS10221	05055273215670	600LPC	28th Nov 23	16th Jun 21
			611LPC	28th Sep 24	23rd May 22
Liquid Assayed Specific Protein Control Level 2	PS2683	05055273204902	585LPC	28th Jun 23	6th Nov 2020
			601LPC	28th Nov 23	7th Oct 21
			612LPC	28th Sep 24	27th Jan 22
			616LPC	28th Nov 22	21st May 21
			634LPC	28th Sep 23	28th Jan 22
			639LPC	28th Jan 24	12th Apr 22

Form No. 6307-TS
REVISION (10)
4th Feb 2019

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

Reason for Action:

The concentration of Rheumatoid Factor (RF) has decreased in Randox 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.

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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 (PS2683and 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

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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.

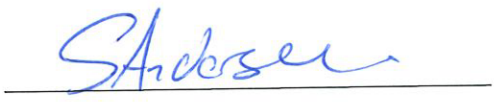
Action to be taken:

- Discard previous IFUs and download the updated IFUs from randox.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@randox.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 Randox Technical Services.

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



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Response Form

Randox Laboratories Ltd
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Tel: +44 (0) 28 9445 1070

Please complete this form *even if you do not have any affected stock*.

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

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Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

Indicate disposition of affected product:

- ❑ No affected stock
- ❑ New Instructions For Use (IFU) downloaded

Customer Details

Company Name	
Address	

Form No. 12187-QA
REVISION (2)
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Total Quantity

Received	
Distributed	

Completed By	Print Name: Signature:	Date	
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@randox.com within five working days.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

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Response Form

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PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

- ❑ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*);

  OR

- ❑ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

Have your customers notified you of any adverse events associated with recalled product?

- ❑ YES
- ❑ NO

If yes, please explain: _____

Form No. 12187-QA
REVISION (2)
17 Jul 2019