



Number : 3668

Title: VITEK®MS – Improvement of the Door Hinges

This MAR applies to: **BOTH CLINICAL AND INDUSTRY**

Catalog Profile:C73
Reference N°/ “System-Product-Service” Name : VITEK®MS instrument ref. 410895, 412550, 410710, 413264
Lot/Serial : ALL
Expiry date: N/A
Required Actions: See section B – Deadline: 30-OCT-2018

Issue Date : October 30, 2017

Section A: Details

Dear colleagues,
We would like to inform you about the following:

1. Product Distribution

Impacted Countries :

	Sold-to pt	Sold to Party Name	Country name	Country code
Subsidiaries	AR01	BIOMERIEUX ARGENTINA	Argentina	AR
	AU01	BIOMERIEUX AUSTRALIA P/L	Australia	NZ
	BR01	BIOMERIEUX BRASIL INDUSTRIA E	Brazil	BR
	CA01	BIOMERIEUX CANADA, INC.	Canada	CA
	CH01	BIOMERIEUX SUISSE S.A.	Switzerland	CH
	CL01	BIOMERIEUX CHILE S.A.	Chile	CL
	CO01	BIOMERIEUX COLOMBIA S.A.S	Colombia	CO
	CZ01	BIOMERIEUX CZ S.R.O.	Czech Republic	AT/HU
	DE01	BIOMERIEUX DEUTSCHLAND GMBH	Germany	DE
	ES01	BIOMERIEUX ESPAÑA, S.A.	Spain	IC
	FR01	BIOMERIEUX S.A	France	FR/MQ
	GB01	BIOMERIEUX UK LTD	United Kingdom	IE
	HK01	BIOMERIEUX CHINA LIMITED	Hong Kong	CN/TW/MO
	IN01	BIOMERIEUX INDIA PVT. LTD	India	IN

Distributors	IT01	BIOMERIEUX ITALIA S.P.A.	Italy	IT
	JP01	SYSMEX BIOMERIEUX CO., LTD	Japan	JP
	KR01	BIOMERIEUX KOREA CO., LTD	South Korea	KR
	MX01	BIOMERIEUX MEXICO SA DE CV	Mexico	MX
	NL01	BIOMERIEUX BENELUX BV	Netherlands	BE/LU
	PL01	bioMerieux Polska Sp. z o.o.	Poland	PL
	PT01	BIOMERIEUX PORTUGAL, LDA	Portugal	PT
	RU02	BIOMERIEUX RUSS LLC,	Russian Fed.	RU
	SE01	BIOMERIEUX SWEDEN AB	Sweden	DK/FI/NO
	SG01	BIOMERIEUX SINGAPORE PTE LTD	Singapore	SG
	TH01	BIOMERIEUX THAILAND LTD	Thailand	TH
	TR01	BIOMERIEUX DIAGNOSTIK A.S.	Turkey	TR
	US01	BIOMERIEUX US	United States	US
	ZA01	BIOMERIEUX SOUTH AFRICA PTY	South Africa	ZA/NA
	1038017	ILEX MEDICAL LTD	Israel	IL
	1035324	BADER SULTAN & BROS CO WLL	Kuwait	KW
	1100455	Gulf Integrated Security Solutions	Kuwait	KW
	1030057	AL JEEL MEDICAL	Saudi Arabia	SA
	1034755	AL HAYAT PHARMACEUTICALS	Utd.Arab Emir.	AE
	1030583	TNC EVERLIGHT PHILIPPINES, INC.	Philippines	PH
	1043421	FAS DIAGNOSTIC GROUP, INC.	Philippines	PH
	1054476	MEDIGENE SDN BHD	Malaysia	MY
	2052125	DIAGNOSTIC SYSTEMS (M) SDN BHD	Malaysia	MY
	1089884	SIMED S.A.	Ecuador	EC
	1030995	YUNYCOM DOO	Serbia	RS
	1037241	INTER BUSINESS 91 LTD	Bulgaria	BG
	1035981	INVERSIONES SAGRAV S.A.	Panama	PA
	1038470	ULTRA DIAGNOSTIC	Egypt	EG
	1035279	ALI ALSUWAIDI TRADING ESTABLISHMENT	Qatar	QA
	1038728	CHERUBINO LTD	Malta	MT
	1031376	BIOTECK S.A.L	lebanon	LB
	1054909	MC QUIPP TECHNISELL	Brunei Daruss.	BN
1049008	OZEL NESIL	Azerbaidjan	AZ	
1070840	DKSH TECHNOLOGY CO LTD	Vietnam	VN	
1091979	SLT LTD	Belarus	BY	
1034890	UAB DIAMEDICA	Lithuania	LT	
1035388	TECNO DIAGNOSTICA S.A.	Costa Rica	CR	
1032570	TUZLA FARM	Bosnia-Herz.	BA	
1076188	LABYMED S.A.	Guatemala	GT	
1029326	PT. ENSEVAL MEDIKA PRIMA	Indonesia	ID	
1054863	SEDA HJ	Turkmenistan	TM	
Direct Customers	2039012	WIEGAND INTERNATIONAL	Kazakhstan	KZ
	1055441	TYM MEDICAL	Cote d'Ivoire	CI

2066061	Italmondo Spa	Montenegro	ME
2037823	Dennis Ringeling	Dutch antilles	AN
2043327	FAMAR S.A.	Grece	GR
2048952	IHU - MEDITERRANEE INFECTION	Senegal	SN

2. Product Description

VITEK® MS is a bacterial and fungal identification system which uses the matrix-assisted laser desorption/ionization (MALDI) mass spectrometry method.

The VITEK® MS is a rapid method for microorganism identifications from clinical cultures.

Microbial specimens are analyzed based on the dynamics of particles projected by a laser shot in a vacuum tube.

The resulting spectrum of mass distribution will be interpreted according to a knowledge database developed by bioMerieux.

3. Context

It has been reported from the field and seen in production that the SAC door can occasionally stick open when operated. It has also been reported that during the annual preventative maintenance, the SAC door hinge shoulder bolt can seize in the hinge block when the door springs are replaced.

A solution to modify and improve the door assembly has been designed and validated by KRATOS.

The modification involves the insertion of a plastic flanged bushing into the hinge.

This has required the expansion of the hole in the hinge block. The bushing reduces the friction between the shoulder bolt and the hinge block, and will not allow the metal surfaces to come into contact.

The performance of the system is not modified by this design change.

New instruments are fitted with the new hinge block assembly design during manufacturing from serial number **51323**.

Instruments already produced or in the field must be updated as needed during the next Preventative Maintenance by the FSE, using the REFERENCE **6204899 VITEK®MS SAC DOOR HINGE KIT**.

The kit includes two hinges with bushings, door springs and shoulder bolts :



The existing 6201051 SAC DOOR KIT OF PARTS is replaced by the updated reference 6205136 :



Hereafter photo of the New Hinge (left with a bearing) versus old design (right):



👉 INSTRUCTION FOR THE ORDERING:

The ordering will be driven directly by the Global Supply Chain in Craaponne to ease the workflow, and make a fair share of the quantities available in stock at launch which cannot cover the total installed base. The stock will be replenished all along the coming year based on the instruments annual Preventative Maintenance forecast.

- **Subsidiaries (except France)**

Your orders will be placed by the Global Supply Chain, based on an allocation determined by your installed base size, for launch quantity.

Please do not place or send any purchase order to Export Sales Admin, Supply Chain will manage.

- **French subsidiary:**

Please place your customer orders according to your PM schedule.

A quantity has been allocated to you according to your installed base size.

- **Distributors:**

Please place your orders as usual according to your PM schedule.

A quantity has been allocated to you according to your installed base.

If you have any additional question or doubt concerning this MAR in general, please do not hesitate to contact the GCS through general email box :

GCS_MICROBIOLOGY@biomerieux.com

Section B: Required actions

According to the table below:

1. Please immediately acknowledge receipt (AR) of this MAR.
2. Please apply the update.
3. Fill the acknowledgement of completion (AC) for this MAR by **(30 – OCTOBER– 2018)**

Subsidiaries using SAP	<ol style="list-style-type: none">1) <u>Acknowledgement of Receipt</u> : Please immediately acknowledge receipt (AR) of this MAR within SAP.2) <u>Acknowledgement of Completion</u> : please also manage the acknowledgement of completion within SAP.
Subsidiaries not using SAP	<ol style="list-style-type: none">1) <u>Acknowledgement of Receipt</u> : Please immediately upload the Acknowledgement of Receipt in LiveLink after signing and completing sections #1 and #2 of the Acknowledgement Form.2) <u>Acknowledgement of Completion</u> : After completing and signing Section #3 before the deadline, please upload the Acknowledgement of Completion in Livelink
Distributors	<ol style="list-style-type: none">1) <u>Acknowledgement of Receipt</u> : Please immediately Acknowledge of Receipt of this MAR by completing sections #1 and #2 of the Acknowledgement Form and sending it by email to fielddactions@biomerieux.com or by fax to +33 4 78 87 21 79.2) <u>Acknowledgement of Completion</u> : After completing and signing Section #3 before the deadline, please send it by email to fielddactions@biomerieux.com or by fax to +33 4 78 87 21 79.

Section Contact Information



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Section D: Acknowledgement Form

Number: 3668 Hinges	Title: MAR - VITEK®MS – Improvement of the Door	Deadline: 30OCT2018
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SECTION 1

Location		
Group Company or Distributor Name(s)	Country	Account #
A		
B		
C		
D		

SECTION 2

Acknowledgement of Receipt (AR)	
Print Name	
Sign Name	
Position	
Date (dd/MMM/yyyy)	

SECTION 3

- Field Action Not Applicable
- Field Action Applicable (Fill the “Acknowledgment of Completion” table below)

Acknowledgement of Completion (AC)								
Group Company or Distributor	1. REF #	2. LOT #	3. Total Received	4. Total Shipped	5. Total On Hand	6. Total Destroyed	7. Total Instruments Affected	9. Total Updates Completed
A	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.

Customer Letter Issue date:	N/A
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Print Name	
Sign Name	
Position	
Date (dd/MMM/yyyy)	