



Brussels, Date

URGENT: FIELD SAFETY NOTICE

Reference: FSCA#5333

GLOBAL FIELD SAFETY NOTICE – Correction VIDAS® Immuno-Assays Multiple references - Substrate error - Potential delayed results

Dear bioMérieux Customer,

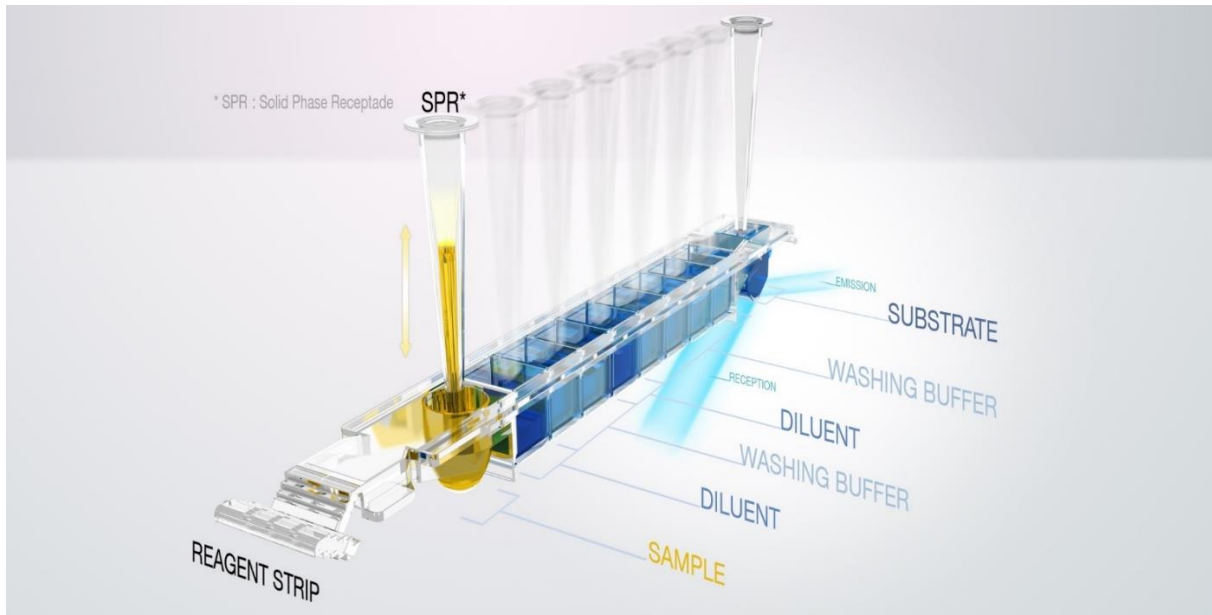
The intent of this letter is to share with you important information regarding clinical VIDAS® Immuno-Assays references products listed below in Table 1. Your laboratory received one/several of the following clinical VIDAS® Immuno-Assays references products and lots.

Description of the issue

Since July 2021, bioMérieux has been receiving an increasing number of complaints linked to a VIDAS® “substrate error”. It prevents the test from being run, therefore leads to a potential delayed results as you need to run another test.

A measurement of the background noise signal (RFU) is made by the VIDAS® system prior to launching the reaction. An acceptable limit is defined during product design for each reference of finished goods. Three values exist as acceptable limits depending on the assay: 300, 350 and 500 RFU. The substrate is present in the last well of the strip of all VIDAS® immuno-assays and allows fluorescence when degraded by the enzyme (PAL).

bioMérieux Benelux s.a./n.v.



The level of fluorescence is then correlated with the results of all tests.

When you are performing a test, if the RFU is higher than the acceptable limit, there is an error message displayed by the system: "Substrate Error". The test is stopped and this alarm prevents the system to provide any result if the RFU value is above the cut-off defined during the product development.

This alarm being present on all the systems of the VIDAS® family, it guarantees that **no false results** can be given in case of a substrate degradation. **This means that there is only a risk of delayed results.**

Investigations were immediately initiated to identify the root-cause, the following were identified:

- All impacted lots of VIDAS® Immuno-assays were conform to the specifications at release.
- The substrate error issue was confirmed on all lots of VIDAS® Immuno-Assays manufactured with substrate batches using a common lot of raw material (4-MUP) that was identified as the most probable common root-cause.
- The scope of the issue was identified on all lots of VIDAS® Immuno-Assays manufactured since February 2021 using substrate batches manufactured with this concerned lot of raw material
- The problem is due to an accelerated degradation of the substrate, which follows a linear model over time leading to RFU acceptable limits being reached before the end of the registered shelf life of the product.
- Kinetic evolution analyzes were performed by measuring substrate RFU of a statistically representative number of VIDAS® immuno-assays retained batches (manufactured with the substrate containing the concerned raw material) at different shelf-lives.

- This model allows us to predict the degradation trend of the substrate using the concerned batch of 4MUP and therefore to revise the expiry dates for each lot of impacted VIDAS® Immuno-assays finished products.
- When used until the revised expiry date, the product continues to perform per its registered performance specifications
- Therefore, a corrective action involving a revised expiration date for all lots of clinical VIDAS® Immuno-assays products (listed in Table 1 below) is required to ensure that the specified products will continue to perform per labelled performance specifications.

We understand this complex matter creates a significant inconvenience. We thank you for your cooperation which is essential to ensure the successful implementation of this corrective action, in order to protect the safety of our patients.

We are currently reworking some lots of VIDAS® Immuno Assays in stock applying a sticker with the revised expiry date on top of the kits. However, to ensure service continuity you may receive, for a short period of time, impacted lots of clinical VIDAS® Immuno-Assays without sticker. All those lots are in the scope of this Urgent Field Safety Notice, and detailed in the different attachments of the table 1.

Impact to Customer/Patient:

In case of substrate error, there is a potential of delayed results. There is no risk of false results

Required actions:

Please determine which product references you currently have in stock that are referenced in Table 1, and implement the actions defined in the applicable tables.

- **For products with remaining shelf life (taking into account the revised expiry date) in Table 1:**
 - Identify products listed in Table 1,
 - Update product expiry date per your internal procedures of the remaining usable lots to meet the new revised expiry date specified in Table 1.
 - Continue product use until revised expiry date.
- Contact your local bioMérieux Customer Service representative to order the replacement products when expired under the revised expiry date

bioMérieux Benelux s.a./n.v.



- As a reminder, please store the VIDAS® references at 2-8°C as described in Product Instructions for Use.
- Please distribute this information to all appropriate personnel in your laboratory, retain a copy in your files, and forward this information to all parties that may use this product, including others to whom you may have transferred our product.
- Complete the Acknowledgement Form in Attachment A and return it to your local bioMérieux representative to confirm receipt of this notice.

bioMérieux is committed to providing our customers with the highest quality product possible.

We sincerely apologize for any inconvenience that this may have caused you. If you require additional assistance or have any questions, your local bioMérieux Customer Service representative will be here to assist you.

e-mail: fieldactions.benelux@biomerieux.com or phone: +31 (0)885 06 47 00

Thank you for your continued use of bioMérieux products,

Sincerely yours,

Customer Relationship Center
bioMérieux Benelux

Table 1: List of impacted clinical VIDAS® Immuno-Assays references products:

Product Reference	Product name	Attached tables
30118	VIDAS® C. difficile Toxin A & B	See table 2
30118-01		
30125	VIDAS® C. difficile GDH	See table 3
30125-01		
30211	VIDAS® TOXO Compétition	See table 4
30308	VIDAS® Anti-HCV	See table 5
30314	VIDAS® Anti-HBc Total II	See table 6
30315	VIDAS® HBs Ag Ultra	See table 7
30318	VIDAS® Anti-HBs Total II	See table 8
30405	VIDAS® HCG	See table 9
30409	VIDAS® Progesterone	See table 10
30409-01		
30421	VIDAS® CK-MB	See table 11
30439	VIDAS® HBc IgM II	See table 12
30443	VIDAS® HIV DUO Ultra	See table 13
30446	VIDAS® Myoglobin	See table 14
30447	VIDAS® HIV DUO Quick	See table 15
30450	VIDAS® B•R•A•H•M•S PCT™	See table 16
30450-01		
30450-30		
30450-86		
30455	VIDAS® D-Dimer Exclusion II™	See table 17
30455-01		
30455-02		
30455-30		
30458	VIDAS® NT-proBNP2	See table 18
30458-30		
30603	VIDAS® Digoxin	See table 19
415386	VIDAS® High sensitive Troponin I	See table 20
415386-30		
418115	VIDAS® Anti-HEV IgM	See table 21
421172-03	VIDAS® NEPHROCHECK®	See table 22
423077	VIDAS® DENGUE NS1 Ag	See table 23
423078	VIDAS® Anti-DENGUE IgM	See table 24



Attachment A: Acknowledgement Form

URGENT: FIELD SAFETY NOTICE

GLOBAL FIELD SAFETY NOTICE – Correction VIDAS® Immuno-Assays Multiple references - Substrate error - Potential delayed results

TO BE RETURNED TO YOUR BIO-MERIEUX CUSTOMER SERVICE AT THE FOLLOWING:

FAX NUMBER: +32 (0)2 793 01 44 OR EMAIL: FIELDACTIONS.BENELUX@BIOMERIEUX.COM

Name of the laboratory: _____

City: _____

Customer number: _____

<p align="center">Instruction:</p> <p>- please add a cross in the for you applicable box of the by you ordered impacted refs/batches (in blue the ones you recently ordered)</p> <p>- please do not forget to add a cross if you encounter an impact on patients' results for the specific reference</p>	30118	VIDAS® C. difficile Toxin A & B
	30118-01	VIDAS® C. difficile Toxin A & B
	30125	VIDAS® C. difficile GDH
	30125-01	VIDAS® C. difficile GDH
	30211	VIDAS® TOXO Compétition
	30308	VIDAS® Anti-HCV
	30314	VIDAS® Anti-HBc Total II
	30315	VIDAS® HBs Ag Ultra
	30318	VIDAS® Anti-HBs Total II
	30405	VIDAS® HCG
	30409	VIDAS® Progesterone
	30409-01	VIDAS® Progesterone
	30421	VIDAS® CK-MB
	30439	VIDAS® HbC IgM II
	30443	VIDAS® HIV DUO Ultra
	30446	VIDAS® Myoglobin
	30447	VIDAS® HIV DUO Quick
	30450	VIDAS® B-R-A-H-M-S PCT™
	30450-01	VIDAS® B-R-A-H-M-S PCT™
	30450-30	VIDAS® B-R-A-H-M-S PCT™
30450-86	VIDAS® B-R-A-H-M-S PCT™	
30455	VIDAS® D-Dimer Exclusion II™	
30455-01	VIDAS® D-Dimer Exclusion II™	
30455-02	VIDAS® D-Dimer Exclusion II™	
30455-30	VIDAS® D-Dimer Exclusion II™	
30458	VIDAS® NT-proBNP2	
30458-30	VIDAS® NT-proBNP3	
30603	VIDAS® Digoxin	
415386	VIDAS® High sensitive Troponin I	
415386-30	VIDAS® High sensitive Troponin I	
418115	VIDAS® Anti-HEV IgM	
421172-03	VIDAS® NEPHROCHECK®	
423077	VIDAS® DENGUE NS1 Ag	
423078	VIDAS® Anti-DENGUE IgM	
I acknowledge receipt of the bioMérieux letter regarding the "VIDAS® Immuno-Assays Multiple references - Substrate Error - Potential delayed results"		
I will implement the required actions regarding impacted lots of VIDAS® as indicated in the Urgent Field Safety Notice		
Have you encountered impact on patients' results, or reports of illness or injury related to the identified issue		

SIGNATURE.....

DATE:

bioMérieux Benelux s.a./n.v.



Table 2: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30118	1008731010	VIDAS CD A.B 60 TESTS	09-Apr-2022	10-Mar-2022
30118	1008926680	VIDAS CD A.B 60 TESTS	08-Jul-2022	01-Jun-2022
30118-01	1008730880	VIDAS C.DIFFICILE TOXIN A&B	09-Apr-2022	10-Mar-2022

Table 3: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30125	1008597480	VIDAS GDH 60 TESTS	18-Apr-2022	25-Jan-2022
30125	1008686700	VIDAS GDH 60 TESTS	06-Jun-2022	03-Mar-2022
30125	1008859220	VIDAS GDH 60 TESTS	03-Sep-2022	13-Jun-2022
30125-01	1008686690	VIDAS C DIFFICILE GDH 60 TESTS	06-Jun-2022	03-Mar-2022

Table 4: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30211	1008615860	VIDAS TOXO COMPETITION 60 TEST	24-Feb-2022	09-Feb-2022
30211	1008864170	VIDAS TOXO COMPETITION 60 TEST	28-Jun-2022	08-Jun-2022

Table 5: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30308	1008624280	VIDAS ANTI-HCV 60 TESTS	30-May-2022	26-Jan-2022
30308	1008837640	VIDAS ANTI-HCV 60 TESTS	14-Sep-2022	26-May-2022
30308	1008722870	VIDAS ANTI-HCV 60 TESTS	20-Jul-2022	25-Mar-2022
30308	1008808970	VIDAS ANTI-HCV 60 TESTS	09-Sep-2022	17-May-2022
30308	1008857200	VIDAS ANTI-HCV 60 TESTS	01-Oct-2022	16-Jun-2022
30308	1008860610	VIDAS ANTI-HCV 60 TESTS	01-Oct-2022	16-Jun-2022

bioMérieux Benelux s.a./n.v.

Table 6: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30314	1008654830	VIDAS ANTI-HBC TOTAL II 60 TEST	11-Mar-2022	23-Feb-2022

Table 7: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30315	1008612250	VIDAS HBS AG ULTRA 60 TESTS	26-Mar-2022	25-Jan-2022
30315	1008614380	VIDAS HBS AG ULTRA 60 TESTS	26-Mar-2022	25-Jan-2022
30315	1008642570	VIDAS HBS AG ULTRA 60 TESTS	22-Apr-2022	23-Feb-2022
30315	1008735620	VIDAS HBS AG ULTRA 60 TESTS	26-May-2022	07-Apr-2022
30315	1008790310	VIDAS HBS AG ULTRA 60 TESTS	05-Jul-2022	17-May-2022
30315	1008790410	VIDAS HBS AG ULTRA 60 TESTS	05-Jul-2022	17-May-2022
30315	1008861610	VIDAS HBS AG ULTRA 60 TESTS	06-Aug-2022	16-Jun-2022

Table 8: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30318	1008719940	VIDAS ANTI HBS TOTAL II 60T	29-Jul-2022	30-Nov-2021
30318	1008830740	VIDAS ANTI HBS TOTAL II 60T	07-Oct-2022	18-Jan-2022
30318	1008865350	VIDAS ANTI HBS TOTAL II 60T	03-Nov-2022	06-Feb-2022

Table 9: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30405	1008714630	VIDAS HCG 60 TESTS	26-Apr-2022	27-Nov-2021
30405	1008747680	VIDAS HCG 60 TESTS	11-May-2022	27-Nov-2021
30405	1008757640	VIDAS HCG 60 TESTS	18-May-2022	19-Dec-2021
30405	1008784120	VIDAS HCG 60 TESTS	03-Jun-2022	01-Jan-2022
30405	1008796930	VIDAS HCG 60 TESTS	02-Jun-2022	09-Jan-2022
30405	1008808600	VIDAS HCG 60 TESTS	14-Jun-2022	09-Jan-2022
30405	1008824160	VIDAS HCG 60 TESTS	17-Jun-2022	25-Jan-2022
30405	1008827550	VIDAS HCG 60 TESTS	16-Jun-2022	25-Jan-2022
30405	1008849560	VIDAS HCG 60 TESTS	01-Jul-2022	05-Feb-2022
30405	1008861770	VIDAS HCG 60 TESTS	08-Jul-2022	05-Feb-2022
30405	1008881760	VIDAS HCG 60 TESTS	15-Jul-2022	15-Feb-2022
30405	1008920140	VIDAS HCG 60 TESTS	06-Aug-2022	27-Feb-2022
30405	1008924590	VIDAS HCG 60 TESTS	05-Aug-2022	22-Mar-2022
30405	1008926200	VIDAS HCG 60 TESTS	18-Aug-2022	22-Mar-2022

Table 10: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30409	1008615920	VIDAS PROGESTERONE 60 TESTS	02-Mar-2022	03-Feb-2022
30409	1008685480	VIDAS PROGESTERONE 60 TESTS	20-May-2022	07-Apr-2022
30409	1008686900	VIDAS PROGESTERONE 60 TESTS	13-Apr-2022	22-Mar-2022
30409	1008730710	VIDAS PROGESTERONE 60 TESTS	29-Apr-2022	04-Apr-2022
30409	1008775650	VIDAS PROGESTERONE 60 TESTS	28-May-2022	09-May-2022
30409	1008816010	VIDAS PROGESTERONE 60 TESTS	10-Jun-2022	09-May-2022
30409	1008816030	VIDAS PROGESTERONE 60 TESTS	10-Jun-2022	09-May-2022
30409	1008873190	VIDAS PROGESTERONE 60 TESTS	08-Jul-2022	23-Jun-2022
30409	1008911230	VIDAS PROGESTERONE 60 TESTS	06-Aug-2022	05-Jul-2022
30409-01	1008685490	VIDAS PROGESTERONE 60 TESTS	13-Apr-2022	22-Mar-2022
30409-01	1008766980	VIDAS PROGESTERONE 60 TESTS	29-Apr-2022	04-Apr-2022
30409-01	1008775630	VIDAS PROGESTERONE 60 TESTS	28-May-2022	09-May-2022
30409-01	1008873180	VIDAS PROGESTERONE 60 TESTS	08-Jul-2022	23-Jun-2022
30409-01	1008911240	VIDAS PROGESTERONE 60 TESTS	06-Aug-2022	05-Jul-2022

Table 11: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30421	1008557760	VIDAS CK MB 30 TESTS	21-Jan-2022	12-Jan-2022
30421	1008934620	VIDAS CK MB 30 TESTS	15-Jul-2022	29-Jun-2022

Table 12: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30439	1008636760	VIDAS HBC IGM II 30 TESTS	12-Mar-2022	23-Feb-2022
30439	1008888750	VIDAS HBC IGM II 30 TESTS	29-Jun-2022	08-Jun-2022

Table 13: Product with and without remaining shelf life (taking into account the revised expiry date)

Table13 a: Product with NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30443	1008675340	VIDAS HIV DUO ULTRA 60 TESTS	30-Mar-2022	13-Sep-2021

Table 13b : Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30443	1008745740	VIDAS HIV DUO ULTRA 60 TESTS	27-Apr-2022	18-Oct-2021
30443	1008829020	VIDAS HIV DUO ULTRA 60 TESTS	29-Jun-2022	19-Dec-2021
30443	1008834410	VIDAS HIV DUO ULTRA 60 TESTS	21-Jun-2022	06-Dec-2021

Table 14: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30446	1008658660	VIDAS MYOGLOBIN 30 TESTS	23-Mar-2022	26-Oct-2021
30446	1008708120	VIDAS MYOGLOBIN 30 TESTS	22-Apr-2022	14-Nov-2021
30446	1008802100	VIDAS MYOGLOBIN 30 TESTS	08-Jun-2022	01-Jan-2022
30446	1008813810	VIDAS MYOGLOBIN 30 TESTS	08-Jun-2022	01-Jan-2022

Table 15: Product with and without remaining shelf life (taking into account the revised expiry date)

Table 15a: Product with NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30447	1008592410	VIDAS HIV DUO QUICK 60 TESTS	31-Jan-2022	07-Aug-2021

Table 15b: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30447	1008680850	VIDAS HIV DUO QUICK 60 TESTS	11-Apr-2022	02-Oct-2021
30447	1008802860	VIDAS HIV DUO QUICK 60 TESTS	13-Jun-2022	27-Nov-2021

bioMérieux Benelux s.a./n.v.

Table 16: Product with and without remaining shelf life (taking into account the revised expiry date)

Table 16a: Product with NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30450	1008591130	VIDAS BRAHMS PROCALCITONIN 60T	15-Aug-2022	20-Sep-2021
30450	1008633310	VIDAS BRAHMS PROCALCITONIN 60T	08-Sep-2022	28-Sep-2021
30450	1008641870	VIDAS BRAHMS PROCALCITONIN 60T	08-Sep-2022	28-Sep-2021
30450-01	1008584190	VIDAS BRAHMS PROCALCITONIN 60T	10-Aug-2022	19-Sep-2021
30450-01	1008603580	VIDAS BRAHMS PROCALCITONIN 60T	22-Aug-2022	20-Sep-2021
30450-86	1008562400	VIDAS BRAHMS PROCALCITONIN 60T	13-Jul-2022	06-Sep-2021
30450-86	1008594750	VIDAS BRAHMS PROCALCITONIN 60T	21-Aug-2022	20-Sep-2021

Table 16b : Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30450	1008661450	VIDAS BRAHMS PROCALCITONIN 60T	21-Sep-2022	26-Oct-2021
30450	1008722440	VIDAS BRAHMS PROCALCITONIN 60T	27-Oct-2022	30-Nov-2021
30450	1008741790	VIDAS BRAHMS PROCALCITONIN 60T	07-Nov-2022	30-Nov-2021
30450	1008769030	VIDAS BRAHMS PROCALCITONIN 60T	24-Nov-2022	31-Dec-2021
30450	1008796890	VIDAS BRAHMS PROCALCITONIN 60T	11-Dec-2022	31-Dec-2021
30450	1008784200	VIDAS BRAHMS PROCALCITONIN 60T	30-Nov-2022	09-Jan-2022
30450	1008817120	VIDAS BRAHMS PROCALCITONIN 60T	15-Dec-2022	24-Jan-2022
30450	1008886330	VIDAS BRAHMS PROCALCITONIN 60T	18-Jan-2023	08-Feb-2022
30450	1008926040	VIDAS BRAHMS PROCALCITONIN 60T	08-Feb-2023	21-Mar-2022
30450-01	1008647850	VIDAS BRAHMS PROCALCITONIN 60T	14-Sep-2022	18-Oct-2021
30450-01	1008748010	VIDAS BRAHMS PROCALCITONIN 60T	14-Nov-2022	30-Nov-2021
30450-01	1008888030	VIDAS BRAHMS PROCALCITONIN 60T	19-Jan-2023	12-Feb-2022
30450-01	1008903210	VIDAS BRAHMS PROCALCITONIN 60T	31-Jan-2023	21-Feb-2022
30450-01	1008926050	VIDAS BRAHMS PROCALCITONIN 60T	08-Feb-2023	21-Mar-2022

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30450-30	1008741800	VIDAS BRAHMS PROCALCITONIN 30T	07-Nov-2022	30-Nov-2021
30450-30	1008926060	VIDAS BRAHMS PROCALCITONIN 30T	08-Feb-2023	21-Mar-2022
30450-86	1008784190	VIDAS BRAHMS PROCALCITONIN 60T	30-Nov-2022	09-Jan-2022
30450-86	1008817140	VIDAS BRAHMS PROCALCITONIN 60T	15-Dec-2022	24-Jan-2022
30450-86	1008671350	VIDAS BRAHMS PROCALCITONIN 60T	29-Sep-2022	26-Oct-2021
30450-86	1008714950	VIDAS BRAHMS PROCALCITONIN 60T	24-Oct-2022	30-Nov-2021
30450-86	1008741810	VIDAS BRAHMS PROCALCITONIN 60T	07-Nov-2022	30-Nov-2021
30450-86	1008769290	VIDAS BRAHMS PROCALCITONIN 60T	24-Nov-2022	31-Dec-2021
30450-86	1008868260	VIDAS BRAHMS PROCALCITONIN 60T	12-Jan-2023	12-Feb-2022
30450-86	1008888040	VIDAS BRAHMS PROCALCITONIN 60T	19-Jan-2023	12-Feb-2022
30450-86	1008892830	VIDAS BRAHMS PROCALCITONIN 60T	19-Jan-2023	12-Feb-2022
30450-86	1008903360	VIDAS BRAHMS PROCALCITONIN 60T	31-Jan-2023	21-Feb-2022

Table 17: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30455	1008589450	VIDAS D DIMER EXCLUSION II 60T	17-Feb-2022	25-Jan-2022
30455	1008815230	VIDAS D DIMER EXCLUSION II 60T	13-Jun-2022	17-May-2022
30455	1008761040	VIDAS D DIMER EXCLUSION II 60T	22-May-2022	28-Apr-2022
30455	1008770900	VIDAS D DIMER EXCLUSION II 60T	31-May-2022	04-May-2022
30455	1008778210	VIDAS D DIMER EXCLUSION II 60T	30-May-2022	28-Apr-2022
30455	1008800130	VIDAS D DIMER EXCLUSION II 60T	03-Jun-2022	08-May-2022
30455	1008815200	VIDAS D DIMER EXCLUSION II 60T	14-Jun-2022	27-May-2022
30455-01	1008696660	VIDAS D DIMER EXCLUSION II 60T US	13-Apr-2022	22-Mar-2022
30455-01	1008761020	VIDAS D DIMER EXCLUSION II 60T US	22-May-2022	28-Apr-2022
30455-01	1008864290	VIDAS D DIMER EXCLUSION II 60T US	15-Jul-2022	16-Jun-2022
30455-01	1008891690	VIDAS D DIMER EXCLUSION II 60T US	27-Jul-2022	29-Jun-2022

bioMérieux Benelux s.a./n.v.



REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30455-02	1008656010	VIDAS D-DIMER EXCLUSION II 60T	23-Mar-2022	03-Mar-2022
30455-02	1008696080	VIDAS D-DIMER EXCLUSION II 60T	13-Apr-2022	22-Mar-2022
30455-02	1008705690	VIDAS D-DIMER EXCLUSION II 60T	18-Apr-2022	07-Apr-2022
30455-02	1008589420	VIDAS D-DIMER EXCLUSION II 60T	16-Feb-2022	26-Jan-2022
30455-02	1008592150	VIDAS D-DIMER EXCLUSION II 60T	23-Feb-2022	03-Feb-2022
30455-02	1008609020	VIDAS D-DIMER EXCLUSION II 60T	26-Feb-2022	03-Feb-2022
30455-02	1008720080	VIDAS D-DIMER EXCLUSION II 60T	18-Apr-2022	07-Apr-2022
30455-02	1008732940	VIDAS D-DIMER EXCLUSION II 60T	04-May-2022	19-Apr-2022
30455-02	1008744900	VIDAS D-DIMER EXCLUSION II 60T	07-May-2022	19-Apr-2022
30455-02	1008756000	VIDAS D-DIMER EXCLUSION II 60T	17-May-2022	04-May-2022
30455-02	1008761030	VIDAS D-DIMER EXCLUSION II 60T	22-May-2022	28-Apr-2022
30455-02	1008762030	VIDAS D-DIMER EXCLUSION II 60T	25-May-2022	28-Apr-2022
30455-02	1008763980	VIDAS D-DIMER EXCLUSION II 60T	24-May-2022	04-May-2022
30455-02	1008771100	VIDAS D-DIMER EXCLUSION II 60T	31-May-2022	04-May-2022
30455-02	1008778230	VIDAS D-DIMER EXCLUSION II 60T	30-May-2022	28-Apr-2022
30455-02	1008781240	VIDAS D-DIMER EXCLUSION II 60T	03-Jun-2022	08-May-2022
30455-02	1008815220	VIDAS D-DIMER EXCLUSION II 60T	14-Jun-2022	27-May-2022
30455-02	1008815240	VIDAS D-DIMER EXCLUSION II 60T	13-Jun-2022	17-May-2022
30455-02	1008864310	VIDAS D-DIMER EXCLUSION II 60T	15-Jul-2022	16-Jun-2022
30455-02	1008891770	VIDAS D-DIMER EXCLUSION II 60T	27/07/2022	29-Jun-2022
30455-02	1008917580	VIDAS D-DIMER EXCLUSION II 60T	17-Aug-2022	27-Jul-2022
30455-02	1008918050	VIDAS D-DIMER EXCLUSION II 60T	31-May-2022	04-May-2022
30455-02	1008918060	VIDAS D-DIMER EXCLUSION II 60T	03-Jun-2022	08-May-2022
30455-30	1008589440	VIDAS D-DIMER EXCLUSION II 30T	16-Feb-2022	26-Jan-2022
30455-30	1008660630	VIDAS D-DIMER EXCLUSION II 30T	23-Mar-2022	03-Mar-2022
30455-30	1008705360	VIDAS D-DIMER EXCLUSION II 30T	13-Apr-2022	22-Mar-2022

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30455-30	1008732910	VIDAS D-DIMER EXCLUSION II 30T	04-May-2022	19-Apr-2022
30455-30	1008763990	VIDAS D-DIMER EXCLUSION II 30T	24-May-2022	04-May-2022
30455-30	1008891780	VIDAS D-DIMER EXCLUSION II 30T	27-Jul-2022	29-Jun-2022
30455-30	1008864300	VIDAS D-DIMER EXCLUSION II 30T	15-Jul-2022	16-Jun-2022

Table 18: Product with and without remaining shelf life (taking into account the revised expiry date)

Table 18a: Product with NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30458	1008693930	VIDAS NT-PROBNP 2 60 TESTS	15-Apr-2022	13-Sep-2021
30458-30	1008699310	VIDAS NT-PROBNP 2 30 TESTS	15-Apr-2022	13-Sep-2021

Table 18b : Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30458	1008747590	VIDAS NT-PROBNP 2 60 TESTS	04-May-2022	11-Oct-2021
30458	1008776240	VIDAS NT-PROBNP 2 60 TESTS	01-Jun-2022	26-Oct-2021
30458	1008838180	VIDAS NT-PROBNP 2 60 TESTS	30-Jun-2022	17-Nov-2021
30458	1008851520	VIDAS NT-PROBNP 2 60 TESTS	30-Jun-2022	17-Nov-2021
30458	1008886400	VIDAS NT-PROBNP 2 60 TESTS	20-Jul-2022	22-Dec-2021
30458	1008894100	VIDAS NT-PROBNP 2 60 TESTS	27-Jul-2022	04-Jan-2022
30458	1008894140	VIDAS NT-PROBNP 2 60 TESTS	27-Jul-2022	04-Jan-2022
30458-30	1008776230	VIDAS NT-PROBNP 2 30 TESTS	01-Jun-2022	26-Oct-2021
30458-30	1008897360	VIDAS NT-PROBNP 2 30 TESTS	27-Jul-2022	04-Jan-2022

Table 19: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
30603	1008824700	VIDAS DIGOXIN - DIG 60 TESTS	22-Jun-2022	27-May-2022

Table 20: Product with and without remaining shelf life (taking into account the revised expiry date)

Table 20a: Product with NO remaining shelf life (taking into account the revised expiry date).

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
415386	1008694760	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	06-Jul-2022	13-Sep-2021
415386	1008727610	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	29-Jul-2022	29-Sep-2021
415386	1008666230	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	19-Jun-2022	25-Aug-2021
415386	1008576310	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	08-May-2022	06-Jul-2021
415386	1008677520	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	01-Jul-2022	25-Aug-2021

Table 20b : Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
415386	1008752990	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	11-Aug-2022	11-Oct-2021
415386	1008768930	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	24-Aug-2022	26-Oct-2021
415386	1008768940	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	21-Aug-2022	30-Oct-2021
415386	1008801930	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	02-Sep-2022	08-Nov-2021
415386	1008809020	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	10-Sep-2022	08-Nov-2021
415386	1008827440	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	17-Sep-2022	18-Nov-2021
415386	1008829290	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	16-Sep-2022	08-Nov-2021
415386	1008843450	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	23-Sep-2022	18-Nov-2021
415386	1008848240	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	30-Sep-2022	30-Nov-2021
415386	1008848270	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	30-Sep-2022	30-Nov-2021
415386	1008867160	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	09-Oct-2022	12-Dec-2021
415386	1008867170	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	09-Oct-2022	12-Dec-2021

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
415386	1008872350	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	08-Oct-2022	08-Dec-2021
415386	1008882110	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	15-Oct-2022	06-Dec-2021
415386	1008886390	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	19-Oct-2022	06-Dec-2021
415386	1008890790	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	18-Oct-2022	08-Dec-2021
415386	1008893760	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	26-Oct-2022	22-Dec-2021
415386	1008901930	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	28-Oct-2022	22-Dec-2021
415386	1008903780	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	29-Oct-2022	04-Jan-2022
415386	1008912850	VIDAS HIGH SENSITIVE TROPONIN I 60 TESTS	04-Nov-2022	04-Jan-2022
415386-30	1008912800	VIDAS HS TROPONIN I 30 TESTS	04-Nov-2022	04-Jan-2022

Table 21: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
418115	1008652560	VIDAS HEV IGM 30T	19-Sep-2022	23-Feb-2022
418115	1008776540	VIDAS HEV IGM 30T	28-Nov-2022	28-Apr-2022
418115	1008868900	VIDAS HEV IGM 30T	16-Jan-2023	14-Jun-2022

Table 22: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
421172-03	1008838860	VIDAS NEPHROCHECK 30 TESTS	22-Sep-2022	26-May-2022

Table 23: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
423077	1008731920	VIDAS DENGUE NS1 AG 60T	26-Oct-2022	07-Apr-2022
423077	1008785470	VIDAS DENGUE NS1 AG 60T	29-Nov-2022	08-May-2022
423077	1008899350	VIDAS DENGUE NS1 AG 60T	03-Jan-2023	08-Jun-2022



Table 24: Product with remaining shelf life (taking into account the revised expiry date)

REF	Lot #	Product Name	Current Expiry date	Revised Expiry date
423078	1008730620	VIDAS ANTI DENGUE IGM 60T	17-Oct-2022	07-Apr-2022
423078	1008781310	VIDAS ANTI DENGUE IGM 60T	27-Nov-2022	28-Apr-2022
423078	1008921610	VIDAS ANTI DENGUE IGM 60T	29-Jan-2023	30-Jun-2022