Quality Assurance (QA) for Health Products

QA Information Notice

IN Nº 2019-09 **Version: 11/09/2019**	**Urgent Field Safety Notice for products manufactured by QIAGEN** **QIAsymphony® SP/AS – Operating the QIAsymphony SP with software verion 5.0.3**

Addressees

- Any person using the products for clinical decision making in the intended use
- Any person having products in stock, in transit or under custom clearance
- Any procurers, buyers with a pending order

Purpose

The Global Fund QA is issuing this information notice to provide recommendations and advises regarding the field safety communication from manufacturer as published by "Agence Nationale de Securite du medicaments et des produits de sante" (ANSM) which is the French National Regulatory Authority.

This notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer	**Qiagen**
Product Name	**QIAsymphony SP instrument with software version 5.0.3**
Product Code	**REF 9001297**
Packaging & Pack size	**n/a**
Batch(es)	**All serial numbers higher or equal to #35437 with preinstalled software version 5.0.3.** **All serial numbers lower than #35437 which were upgraded with software version 5.0.3.**
Expiry Date	**n/a**

Background

The QIAsymphony SP instrument is designed to perform automated purification of nucleic acids. It is intended to be used only in combination with QIAsymphony kits indicated for use with the QIAsymphony SP for the applications described in the kit handbooks.

The QIAsymphony SP is intended for use by professional users, such as technicians and physicians trained in molecular biological techniques and the operation of the QIAsymphony SP instrument.

No incident with regards to these products has been reported to Global Fund from regulatory authorities or principle recipients for the moment.

Nature of defect(s)

Details of defect or problem.	**When a multilot analysis is performed using the continuous loading and 2D barcode integration functionality, an incorrect 2D barcode can be assigned to the samples in the SP result file. The results file corresponding to the first analysis is correct. For subsequent analyzes, the 2D bar code corresponding to the eluate ID assigned to each sample is incorrect (see Figure 1 in annex 1). For further details see annex 1.**
Is there any evidence or suspicion of a risk to public health / patient safety?	**The defect could lead to delayed results or incorrect patient reporting**
Extent of the problem (eg. how many batches).	**Information not available for the moment.**
Extent of distribution of the product / batch (es).	**Worldwide distribution envisaged but distribution to Global Fund principal recipients limited to the following countries based on current data available:** • **Afghanistan** • **Egypt** • **Guyana** • **Iran (Islamic Republic)** • **Kazakhstan** • **Kosovo** • **Kyrgyzstan** • **Nepal** • **Niger** • **Pakistan** • **Philippines** • **Syrian Arab Republic** • **Tajikistan** • **Timor-Leste** • **Uzbekistan** • **Western Asia (Region)**
Number of patients potentially impacted	**No impacted patients known**

Action/Investigations taken

- Global Fund QA has been informed of a safety action carried out by Qiagen in France. The affected users received the attached mail (25/07/2019) (see annex 1). It is recommended to distribute this information to the laboratories using Qiagen QIAsymphony SP.
- An investigation in collaboration with the manufacturer for the equipment communicated by PRs in PQR found that machines procured by the PRs for Guyana, Nepal, Philippines and Tajikistan are not affected.
- Procurement agents of PPM have been informed by Global Fund about this event.

Next Steps

Based on the information available to date and until further notice, the following actions are recommended by The Global Fund QA:

- PRs to identify and inform impacted laboratories about this Information Notice.
- PRs are advised to quarantine the QIAsymphony SP equipment with a serial number greater than or equal to 35437 and to check if software version 5.0.3 is installed on the device. (Software version 5.0.3 is preinstalled on devices with this serial numbers). In this case follow the Field Safety Notice.
- PRs are advised for QIAsymphony SP equipment with a serial number lower than 35437 to identify software version, which is installed on the device. The cases are possible:
    - Case 1: If the software version has been upgraded to 5.0.3. follow the advice of the manufacturer as indicated in the Field Safety Notice.
    - Case 2: If the software is not 5.0.3 no action is needed.
- PRs to stop to use the products for clinical decision making while avoiding testing disruptions and unless needed for exceptional medical circumstances. We encourage to seek advice of the laboratory specialist and to contact the relevant disease advisor.
- We advise the PR to check any ongoing procurement conducted for the country with the manufacturer or the procurement agent if the field safety notice is applicable and to continue distribution of the products within the supply chain until the end destination (ie the laboratories) and then to quarantine.

Contacts

This IN does not require specific written response from PR. PRs should copy The Global Fund QA Team of any correspondence regarding the matter for follow-up.

Please direct the respective answers and any questions about this matter to the technical contacts listed below

Organisation	**Name / Function**	**E-mail address**
Global Fund	René Becker-Burgos, QA Specialist Diagnostic Products	Rene.Becker-Burgos@theglobalfund.org
Global Fund	Eileen Burke, Laboratory Specialist	Eileen.burke@theglobalfund.org

René Becker-Burgos, Quality Assurance Specialist Diagnostic Products

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Germany

16 July 2019

Urgent Field Safety Notice: QIAsymphony SP, Ref: 9001297 – Software 5.0.3

Dear QIAsymphony customer,

We would like to inform you that we have identified a specific issue that you might come across on your QIAsymphony. This issue has been observed **only** in QIAsymphony software version 5.0.3 when using the 2D bar code integration feature with continuous loading of the QIAsymphony SP. Continuous loading is when additional batches are defined and assigned to the same elution rack as a batch that has already been started.

Description of the issue

When performing a multi-batch run using continuous loading in combination with the 2D bar code integration functionality, **an incorrect 2D bar code assignment can be made to samples within the SP results file**. The associated rack file for the run is not affected by this issue. It contains the correct 2D barcode assignments so there is no loss of traceability tracking.

The Sample ID assigned during QIAsymphony batch definition and the position of the eluate on the elution rack are not affected.

Potential Risks Associated with the Issue

The results file for the first run are correct. Subsequent runs will have the incorrect 2D barcode eluate ID assigned for each sample (see Figure 1)**. If 2D bar code eluate IDs are not checked against the sample ID prior to downstream application, the incorrect tube may be selected and it could lead to delayed results or incorrect patient reporting.**

Actions to be Taken by the Customer/User:

Discontinue use of the workflow in the following specific conditions:

- QIAsymphony software version 5.0.3 when **using** the 2D bar code integration feature **with** continuous loading.

Please note that the 2D bar code labware, continuous loading, and Software 5.0.3 can still be used independently of the integration feature.

If you believe you may have been affected by this issue, please see below for advice on how to detect and resolve any mis-assignments.

Detection of Affected Batches

If you suspect that your runs may be affected, this issue can be easily detected using the HTML version of the SP results file.

In the “Detailed Information for Batch” section of the SP results file, the Sample ID entered at QIAsymphony batch definition and the assigned 2D barcode can be seen. The data in the Sample ID column is a combination of both identifiers created for reporting purposes. The Sample ID has not been changed.

In the example shown below, it can be seen that the 2D bar code value has been correctly assigned to samples 1 – 8 for the first batch (2000318). In the second batch (2000319), the 2D barcode values have been repeated from the first batch and incorrectly assigned to samples 9 – 16.

Detailed Information for Batch 2000318

Messages

Time	Message ID	Message
17:52:07	123456	Error message example
17:53:07	30603	Batch state changed, batch finished

Samples

Sample ID	Labware	Input position	Type	Liquid-level detection	Output position
Sample 1 TUBE000001	BD_FIX_#352051 FalconPP 17x100	1	S	N	A:1
Sample 2 TUBE000002	BD_FIX_#352051 FalconPP 17x100	2	S	N	B:1
Sample 3 TUBE000003	BD_FIX_#352051 FalconPP 17x100	3	S	N	C:1
Sample 4 TUBE000004	BD_FIX_#352051 FalconPP 17x100	4	S	N	D:1
Sample 5 TUBE000005	BD_FIX_#352051 FalconPP 17x100	5	S	N	E:1
Sample 6 TUBE000006	BD_FIX_#352051 FalconPP 17x100	6	S	N	F:1
Sample 7 TUBE000007	BD_FIX_#352051 FalconPP 17x100	7	S	N	G:1
Sample 8 TUBE000008	BD_FIX_#352051 FalconPP 17x100	8	S	N	H:1

Detailed Information for Batch 2000319

Messages

Time	Message ID	Message
17:53:07	123456	Error message example
17:54:07	30603	Batch state changed, batch finished

Samples

Sample ID	Labware	Input position	Type	Liquid-level detection	Output position
Sample 9 TUBE000001	BD_FIX_#352051 FalconPP 17x100	1	S	N	A:2
Sample 10 TUBE000002	BD_FIX_#352051 FalconPP 17x100	2	S	N	B:2
Sample 11 TUBE000003	BD_FIX_#352051 FalconPP 17x100	3	S	N	C:2
Sample 12 TUBE000004	BD_FIX_#352051 FalconPP 17x100	4	S	N	D:2
Sample 13 TUBE000005	BD_FIX_#352051 FalconPP 17x100	5	S	N	E:2
Sample 14 TUBE000006	BD_FIX_#352051 FalconPP 17x100	6	S	N	F:2
Sample 15 TUBE000007	BD_FIX_#352051 FalconPP 17x100	7	S	N	G:2
Sample 16 TUBE000008	BD_FIX_#352051 FalconPP 17x100	8	S	N	H:2

Figure 1 Results File

In the event that a run has been affected, the correct 2D bar code assignments can be obtained from the rack file. The rack file is in an XML file but can be opened in Microsoft Excel to provide a table as shown below.

	S	T	U	V	W	X
	SampleId	Type11	TubeBarcode	Type12	Type13	PositionName
	Sample 1	String	TUBE000001	String	String	A:1
	Sample 2	String	TUBE000002	String	String	B:1
	Sample 3	String	TUBE000003	String	String	C:1
	Sample 4	String	TUBE000004	String	String	D:1
	Sample 5	String	TUBE000005	String	String	E:1
	Sample 6	String	TUBE000006	String	String	F:1
	Sample 7	String	TUBE000007	String	String	G:1
	Sample 8	String	TUBE000008	String	String	H:1
	Sample 9	String	TUBE000009	String	String	A:2
	Sample 10	String	TUBE000010	String	String	B:2
	Sample 11	String	TUBE000011	String	String	C:2
	Sample 12	String	TUBE000012	String	String	D:2
	Sample 13	String	TUBE000013	String	String	E:2
	Sample 14	String	TUBE000014	String	String	F:2
	Sample 15	String	TUBE000015	String	String	G:2
	Sample 16	String	TUBE000016	String	String	H:2

Figure 2 Rack File viewed in excel

QIAGEN's commitment to resolving the issue

QIAGEN recognize that this issue may impact your workflow and we are working to address it in a software update and it will be communicated as soon as possible.

IMPORTANT NOTE TO IMPORTERS, DISTRIBUTORS, and COMMERCIAL PARTNERS

Please quarantine your QIAsymphony SP inventory with the software version 5.0.3. Serial Numbers **35437** and higher are pre-installed with software version 5.0.3. Please also notify your customers with this letter and request acknowledgement accordingly. **QIAGEN will contact you with further instructions**

Completion of the Acknowledgement of Receipt form

To ensure that all affected users are notified and according to applicable national statutory provisions, we are obliged to provide proof of notification in the market to the authorities. Therefore, please complete and sign the included Acknowledgement of Receipt form and email it to QIAGEN Technical Services at **techservice-eu@qiagen.com** or fax it to **+49 (0)2103-29-22400**.

We regret any inconvenience caused by this situation. If you have further questions, please contact QIAGEN Technical Services Department.

Please visit the following webpages for contact information:

- QIAGEN Subsidiaries: **https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/**
- QIAGEN Commercial Partners and Importers: **https://www.qiagen.com/about-us/contact/global-contacts/distributors-and-importers/**

Best Regards

Your QIAGEN team

QIAsymphony SP, Ref: 9001297 – Software 5.0.3
Acknowledgement of Receipt form

(Please complete form using block letters)

I hereby acknowledge that I have received, read and understood the included Urgent Field Safety Notice described above. We have taken the necessary actions as suggested by this notice:

- The information was forwarded to all individuals and departments within our organization using this product. The notice was forwarded to the end user.
- We reviewed this notice with our laboratory/medical director.
- For commercial partners only: This notice was forwarded to our customers.
- For commercial partners only: We ceased the distribution of the affected products. We followed-up on the Acknowledgements of Receipt with our customers.

Laboratory/Company name:	
Instrument serial number(s):	
Please confirm the discontinued use of the 2D bar code function with continuous loading? ☐ **YES** **DATE:** _____ ☐**N/A** (not using the 2D barcode with continuous loading)	
Address:	
Contact name:	Title:
Email address:	Phone number:
Signature:	Date:

QIAGEN GmbH
QIAGEN Strasse 1
40724 Hilden
Allemagne

16 Juillet 2019

Avis de sécurité urgent : QIAsymphony SP, réf. : 9001297 – Logiciel 5.0.3

Chère cliente, cher client QIAsymphony,

Nous souhaitons vous informer de la détection d'un problème spécifique que vous êtes susceptible de rencontrer avec votre QIAsymphony. Ce problème a été observé **uniquement** avec la version 5.0.3 du logiciel QIAsymphony lors de l'utilisation de la fonctionnalité d'intégration des codes-barres 2D avec chargement en continu du QIAsymphony SP. Le chargement en continu consiste à définir et à attribuer des lots supplémentaires au même portoir d'élution qu'un lot déjà en cours d'analyse.

Description du problème

Lorsqu'une analyse multilot est effectuée à l'aide du chargement en continu et de la fonctionnalité d'intégration des codes-barres 2D, **un code-barres 2D incorrect peut être attribué aux échantillons dans le fichier de résultats SP**. Ce problème n'affecte pas le fichier de portoir de l'analyse, qui contient les bonnes attributions de codes-barres 2D. La traçabilité est donc maintenue.

L'ID d'échantillon attribué durant la définition du lot sur QIAsymphony et la position de l'éluat sur le portoir d'élution ne sont pas affectés.

Risques potentiels associés au problème

Le fichier de résultats correspondant à la première analyse est correct. Pour les analyses suivantes, le code-barres 2D correspondant à l'ID d'éluat attribué à chaque échantillon est incorrect (voir figure 1). **Si les codes-barres 2D correspondant aux ID d'éluat ne sont pas vérifiés par rapport aux ID d'échantillon avant l'application en aval, le mauvais tube risque d'être sélectionné, ce qui peut entraîner un retard dans les résultats ou la communication de résultats patients erronés.**

Actions devant être menées par le client/l'utilisateur :

Cesser d'utiliser cette procédure dans les conditions spécifiques suivantes :

- Logiciel QIAsymphony version 5.0.3 et **utilisation** de la fonctionnalité d'intégration de codes-barres 2D **avec** chargement en continu.

Notez que vous pouvez continuer à utiliser le matériel de laboratoire à code-barres 2D, le chargement en continu et le logiciel 5.0.3 indépendamment de la fonctionnalité d'intégration.
Si vous croyez avoir été affecté par ce problème, reportez-vous aux conseils ci-dessous pour détecter et résoudre les erreurs d'attribution.

Détection des lots affectés

Si vous pensez que vos analyses ont pu être affectées, vous pouvez facilement détecter le problème à l'aide de la version HTML du fichier de résultats SP.

Dans la section « Detailed Information for Batch » (Informations détaillées sur le lot), vous pouvez voir l'ID d'échantillon saisi lors de la définition du lot sur QIAsymphony ainsi que le code-barres 2D. Les données figurant dans la colonne « Sample ID » (ID d'échantillon) combinent les deux identifiants à des fins de reporting. L'ID d'échantillon n'a pas été modifié.

Dans l'exemple ci-dessous, vous pouvez voir que la valeur de code-barres 2D a été correctement attribuée aux échantillons 1 à 8 pour le premier lot (2000318). Dans le second lot (2000319), les valeurs de codes-barres 2D ont été répétées à partir du premier lot et attribuées par erreur aux échantillons 9 à 16.

Detailed Information for Batch 2000318

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Sample 4 TUBE000004	BD_FIX_#352051 FalconPP 17x100	4	S	N	D:1
Sample 5 TUBE000005	BD_FIX_#352051 FalconPP 17x100	5	S	N	E:1
Sample 6 TUBE000006	BD_FIX_#352051 FalconPP 17x100	6	S	N	F:1
Sample 7 TUBE000007	BD_FIX_#352051 FalconPP 17x100	7	S	N	G:1
Sample 8 TUBE000008	BD_FIX_#352051 FalconPP 17x100	8	S	N	H:1

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Sample 13 TUBE000005	BD_FIX_#352051 FalconPP 17x100	5	S	N	E:2
Sample 14 TUBE000006	BD_FIX_#352051 FalconPP 17x100	6	S	N	F:2
Sample 15 TUBE000007	BD_FIX_#352051 FalconPP 17x100	7	S	N	G:2
Sample 16 TUBE000008	BD_FIX_#352051 FalconPP 17x100	8	S	N	H:2

Figure 1 Fichier de résultats

Si une analyse a été affectée, vous pouvez récupérer les bonnes attributions de codes-barres 2D à partir du fichier de portoir. Le fichier de portoir est un fichier XML qui peut être ouvert dans Microsoft Excel sous forme d'un tableau tel qu'illustré ci-dessous.

	S	T	U	V	W	X
	SampleId	Type11	TubeBarcode	Type12	Type13	PositionName
	Sample 1	String	TUBE000001	String	String	A:1
	Sample 2	String	TUBE000002	String	String	B:1
	Sample 3	String	TUBE000003	String	String	C:1
	Sample 4	String	TUBE000004	String	String	D:1
	Sample 5	String	TUBE000005	String	String	E:1
	Sample 6	String	TUBE000006	String	String	F:1
	Sample 7	String	TUBE000007	String	String	G:1
	Sample 8	String	TUBE000008	String	String	H:1
	Sample 9	String	TUBE000009	String	String	A:2
	Sample 10	String	TUBE000010	String	String	B:2
	Sample 11	String	TUBE000011	String	String	C:2
	Sample 12	String	TUBE000012	String	String	D:2
	Sample 13	String	TUBE000013	String	String	E:2
	Sample 14	String	TUBE000014	String	String	F:2
	Sample 15	String	TUBE000015	String	String	G:2
	Sample 16	String	TUBE000016	String	String	H:2

Figure 2 Fichier de portoir affiché dans Excel

QIAGEN s'engage à résoudre le problème

QIAGEN reconnaît que ce problème peut affecter vos procédures de travail et nous nous efforçons d'y remédier par une mise à jour du logiciel qui vous sera communiquée dès que possible.

REMARQUE IMPORTANTE POUR LES IMPORTATEURS, DISTRIBUTEURS et PARTENAIRES COMMERCIAUX

Veuillez mettre en quarantaine votre stock de QIAsymphony SP munis de la version 5.0.3 du logiciel. La version 5.0.3 du logiciel est préinstallée sur les appareils ayant un numéro de série supérieur ou égal à **35437**. Veuillez transmettre cette lettre à vos clients en leur demandant d'en accuser réception. **QIAGEN vous contactera avec d'autres instructions**

Formulaire d'accusé de réception à compléter

Pour nous assurer que tous les utilisateurs concernés sont avertis et conformément aux dispositions légales en vigueur au niveau national, nous sommes tenus de fournir aux autorités une preuve de distribution d'un avis sur le marché. Par conséquent, veuillez remplir et signer le formulaire d'accusé de réception ci-joint et

l'envoyer par e-mail aux services techniques de QIAGEN à l'adresse **techservice-eu@qiagen.com** ou par fax au **+49 (0)2103-29-22400**.

Nous vous prions de nous excuser pour la gêne occasionnée. Pour toute autre question, n'hésitez pas à contacter les services techniques de QIAGEN.

Pour obtenir nos coordonnées, rendez-vous sur les pages Web suivantes :

- Filiales de QIAGEN : **https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/**
- Partenaires commerciaux et importateurs QIAGEN : **https://www.qiagen.com/about-us/contact/global-contacts/distributors-and-importers/**

Bien cordialement,

Votre équipe QIAGEN

QIAsymphony SP, réf. : 9001297 – Logiciel 5.0.3
Formulaire d'accusé de réception

(Veuillez remplir ce formulaire en lettres capitales)

Je confirme avoir reçu, lu et compris l'avis de sécurité urgent ci-joint décrit ci-dessus. Nous avons mené les actions nécessaires suggérées dans cet avis :

- Les informations ont été transmises à toutes les personnes et à tous les services de notre organisation utilisant ce produit. L'avis a été transmis à l'utilisateur final.
- Nous avons étudié cet avis avec notre directeur de laboratoire/médical.
- À l'attention des partenaires commerciaux uniquement : cet avis a été transmis à nos clients.
- À l'attention des partenaires commerciaux uniquement : nous avons cessé la distribution des produits défectueux. Nous avons envoyé à nos clients un formulaire d'accusé de réception.

Nom du laboratoire / de la société :	
Numéro(s) de série d'instrument(s) :	
Veuillez confirmer que vous avez cessé d'utiliser la fonctionnalité d'intégration des codes-barres 2D avec chargement en continu. ☐ **OUI DATE :** _____ ☐**S.o.** (pas d'utilisation des codes-barres 2D avec chargement en continu)	
Adresse :	
Nom du contact :	Fonction :
Adresse e-mail :	Numéro de téléphone :
Signature :	Date :