

Preventative Action / Process Improvement Final Report

2022-PA-0005

Section:	Toxicology						
Associated:	Vendor,	Initiated: 7/27/2022	TargetDate: 9/28/2022				
Associated II:	,	External:	Completed: 8/3/2022				
Opener: ,		Class:	Confirm on:				
IR Number(s):	multiple						
Description:	A spike in DFE evaluate poter	coccurrences related to a single lot presents a tial sources.	preventative action opportunity to				
Notes:	Date	Comments					
	7/27/2022 Meeting held with Tox Supervisor Gallegos, Tox personnel, QA team and Administrator						
		Discussed spike in DFE occurrences and pote	ential sources.				
	Determined that the presence of DFE (when at a trace level) cannot be excluded as an artifact related to the tube or from the manufacturing process. The artifact level occurrences were all isolated to a single blood kit lot number. The potential for an internal source introducing DFE during analysis was eliminated based on additional testing with the laboratory. Determined that the risk for the presence of DFE in evidentiary samples being unrelated to the subject is too high to draw a conclusion as to the source. Report statements for items with occurrences of DFE in artifact levels found in vials with the lot number will be limited to noting the presence only of DFE but no inference as to the source.						
		Police supply was notified and recalled all unused kits with the suspected lot number. The preventative removal of the vials form use will mitigate risk to additional occurrences.					
		The vendor was also notified of the issue and was unable to provide any additional information.					
		Preventative actions complete. Closure pending release of affected reports.					
		Related cases include:					
		2022-00000713532 2022-00000771106 2022-00000809109 2022-0000809423 2022-0000809500 2022-0000809746 2022-0000818681 2022-0000846635 2022-00000846635 2022-00000854699 2022-00000914044 2022-00000914945 2022-00000977575 2022-00000977575 2022-00000977575 2022-0000097575 2022-00000985772 2022-00000985772 2022-00000985772					

8/2/2022

Meeting held with members of City of Phoenix Prosecutors office and Toxicology and QA staff. Discussed 20 cases and provided background. Provided list of 20 reports via email.



Preventative Action / Process Improvement Final Report 2022-PA-0005

8/3/2022 Tox Supv Gallegos notified MCAO representatives and provided list of affected reports.

8/3/2022 Notification received from Tox Supv Gallegos that all related reports have been finalized.

Preventative actions substantially complete.

Research into spike of DFE occurrences related to a single lot strongly indicates the trace or artifact level presence of DFE cannot be attributed to the individual. The kit supplier was contacted and replied that they are contacting the manufacturing plant, no followup response received to date.

Customers (traffic bureau, MCAO, City of Phoenix) were notified and actions taken to address the reporting language to prevent an unwarranted conclusion being drawn.

Any additional customer notifications or actions to be taken as necessary or applicable.

A51334

Closed.

NA

Analyst (if applicable) Jell A4710 Supervisor or Technical Lead (if applicable

D	ate
C	08/03/2022
D	ate
	8/3/2022
D	ate
D	ate
С	8/03/2022
D	ate
C	8/03/2022
D	ate

Assistant Quality Manager

Assistant Administrator

John Krell A3492 Quality Manager

Benjamin Swanholm

Nancy Crump A3842 ABA for JW Lab Administrator

Kelley A Merwin

From: Sent: To:	Amanda B Gallegos Thursday, July 28, 2022 9:52 AM
Cc:	John E Knell; Kelley A Merwin Jody M Wolf; Benjamin S Swanholm; John J Musselman; Gayle M Swanson; Donald J Stenberg
Subject: Follow Up Flag:	Increased presence of DFE in recent casework
Flag Status:	Flagged

Hi John,

In recent months, the Toxicology section has noticed an abnormal increase in the presence of 1,1-difluoroethane (DFE), which has been detected during routine alcohol/volatile analysis using the HSGC-FID instruments (20 cases from 5/17/22-7/26/22). All of these cases were collected with the same Tri-Tech blood kit lot# 67671. In total, the laboratory has analyzed approximately 380 total cases from this specific blood kit lot# using the HSGC alcohol method, thus approximately 5% of the cases from lot# 67671 that were tested indicated the presence of DFE. To provide context, over the 10-month period of July 2021-April 2022, the Toxicology section confirmed the presence of DFE in only 10 cases (4 of which were Phoenix PD cases, 6 were outside agency cases).

The presence of DFE has no adverse impact on the ethanol concentration, drug analysis processes, or any results that have been reported. DFE is an analyte that our laboratory has the capability to confirm, thus when the first few cases were identified they were forwarded for confirmation testing and DFE was confirmed. The samples with DFE indicated were randomly spread out over a number of analytical batches, performed by multiple analysts on both the HSGC instruments at our laboratory, which assisted in ruling out the possibility of DFE introduction during the analytical process. As the number of cases increased, we put a hold on forwarding these samples for confirmation. As a result, there are some cases where no confirmation testing for DFE has been conducted. Details from those cases were compiled to include location of the blood draw, phlebotomist, etc. At the conclusion of that research, the only common factor was determined to be the specific blood kit lot# 67671. We have contacted Police Supply to have the remainder of those kits recalled in order to prevent any additional occurrences. Please let me know if you need any additional details regarding the steps we have taken and information we have gathered thus far, or if you have any questions related to this issue.

Currently, we are unable to determine the source of the DFE and cannot rule out the possibility of it being an artifact in the blood tubes rather than a substance present in the blood sample as a result of the individual inhaling/abusing DFE. Given the information available, is it appropriate to finalize these reports as the Toxicology service type (rather than the Toxic Vapor service type), including statements such as the following for any cases that indicate the presence of DFE from lot# 67671:

(for samples where confirmation testing was performed)

1,1-difluoroethane (DFE) was detected in the blood sample, however no conclusions or inferences can be drawn regarding the source.

(for samples where DFE is indicated on the alcohol analysis but no further testing has been conducted) 1,1-difluoroethane (DFE) was indicated in the blood sample, however no further testing was performed and no conclusions or inferences can be drawn regarding the source.

2022-PA-0005 Rg-lof 16

See below for a list of the 20 IR#s that indicate the presence of DFE associated with blood kit lot# 67671, the batch data the case is associated with is also included, these were analyzed during the date range of 5/17/22-7/26/22:

IR	batch data
2022-00000713532	jsh051722
2022-00000771106	kw052622
2022-00000796400	ni060222
2022-00000809109	ni060222
2022-00000809423	ni060222
2022-00000809500	ni060222
2022-00000809746	ni060222
2022-00000818681	djs060722
2022-00000840503	djs060922
2022-00000846635	djs060922
2022-00000854699	djs060922
2022-00000898983	gms062222
2022-00000914044	gms062222
2022-00000914945	gms062222
2022-00000977240	kw070522
2022-00000977575	kw070522
2022-00000985772	kw070722
2022-00000992102	kw070722
2022-00001004865	rb070822
2022-00001094894	gms072622

Amanda Gallegos, M.S., D-ABFT-FT

Forensic Science Section Supervisor, Toxicology Section Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860



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2022. PA-005

John E Knell

From: Sent: To: Subject: Amanda B Gallegos Tuesday, August 2, 2022 11:55 AM Benjamin S Swanholm; John E Knell FW: IR#s with DFE indicated - blood kit lot# 67671

FYI

ID

Amanda Gallegos, M.S., D-ABFT-FT Forensic Science Section Supervisor, Toxicology Section Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860



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From: Amanda B Gallegos Sent: Tuesday, August 2, 2022 11:55 AM

To: Sarah DeJong <sarah.dejong@phoenix.gov>; Gary Shupe <gary.shupe@phoenix.gov>; Chelsea Stacey <chelsea.stacey@phoenix.gov>

Subject: IR#s with DFE indicated - blood kit lot# 67671

IR	
2022-00000713532	
2022-00000771106	
2022-00000796400	
2022-00000809109	
2022-00000809423	
2022-00000809500	
2022-00000809746	
2022-00000818681	
2022-00000840503	
2022-00000846635	
2022-00000854699	
2022-00000898983	
2022-00000914044	
2022-00000914945	
2022-00000977240	
2022-00000977575	

2022- PA-0005

2022-0000985772 2022-00000992102 2022-00001004865 2022-00001094894

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2022-0005

John E Knell

From:	Amanda B Gallegos
Sent:	Tuesday, August 2, 2022 11:52 AM
То:	Sarah DeJong; Gary Shupe; Chelsea Stacey
Cc:	Benjamin S Swanholm; John E Knell
Subject:	FW: Blood Kits in stock

FYI – see below for information related to when the specific blood kit lot#67671 was received (4/22/22) and where the kits were distributed.

When I spoke to Jason this morning he indicated that he already notified Traffic Bureau to include phlebotomists/motors and that he had already collected kits and returned them to Police Supply.

Amanda Gallegos, M.S., D-ABFT-FT

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From: Shannon M Reyes <Shannon.Reyes@phoenix.gov> Sent: Monday, August 1, 2022 2:26 PM

To: Amanda B Gallegos <Amanda.Gallegos@phoenix.gov> Subject: Re: Blood Kits in stock

So happy I was able to provide some information to help!

Contact for Traffic Bureau will be, Jason Wainwright 602-495-6787 Office and cell 602-471-4575. Jason is the Equipment Coordinator and a great resource. If for some reason he does not have the answer he will know exactly who to contact to get it.

Please let me know if you need any other information. Hopefully we can find the the kits that are still out there.

2022- PA-UUS

5

Thank you, Shannon

Shannon Reyes A5256 Supply Supervisor Property Management Unit Phoenix Police Department Desk: (602) 256-4306 <u>shannon.reyes@phoenix.gov</u>



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From: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Sent: Monday, August 1, 2022 2:13 PM To: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Subject: RE: Blood Kits in stock

Thank you so much for putting this list together, this is great information !!

I know you issues a recall for Lot# 67671, which based on the number of kits you received back (101) and the approximately 400 kits we have accounted for being received in casework for the lab, it seems there may still potentially be unused kits out there from Lot# 67671. With a significant number of kits being distributed to Traffic Bureau from that lot (640 kits), who would you recommend that I contact that would be able to figure out how those were distributed (DUI vans, specific phlebotomists, motors, etc.)?

Amanda Gallegos, M.S., D-ABFT-FT Forensic Science Section Supervisor, Toxicology Section

Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860



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From: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Sent: Monday, August 1, 2022 12:41 PM

To: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Subject: Re: Blood Kits in stock

Hi Amanda,

I listed below the research we conducted on orders received and where they were supplied to, listing the date and amounts. I might have missed something you needed, please just let me know if you need anything further.

This was our first initial order for blood kits. PO 4400699508 - this was ordered 8/26/2021 and delivered 1/13/22 = Lot# 65339

400- 45 kits from 1/19-3/23 500-15 kits from 1/19-3/17 600- 60 kits from 1/19-3/11 700- 82 kits from 1/19-3/23 800- 88kits from 1/19-3/11 900- 70 kits from 1/18-3/23 VCB- 29 kits from 1/19-3/14 TRAFFIC- 500-1/14/2022 300-25 1/19/2022 200-90 1/20/22

The order for Blood Kits with LOT **#67671** was received 4/22/2022. Since then we received another blood kit order on 6/21/2022.

I went back in system from 4/22/2022 to 7/1/2022 400-50 on 4/26/2022 500- 5 on 4/26/2022 600- 55 kits from4/26-6/28

2022-PA-UNS

700- 30 kits from 4/27-5/26 800- 45 kits from 5/3-6/22 900-75 kits from 4/26-6/21 VCB-26 kits from4/26-5/26 TRAFFIC- 640 kits from 4/26-6/17

Thank you, Shannon

Shannon Reyes A5256 Supply Supervisor Property Management Unit Phoenix Police Department Desk: (602) 256-4306 shannon.reyes@phoenix.gov



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From: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Sent: Thursday, July 28, 2022 4:40 PM To: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Subject: Re: Blood Kits in stock

Have a great weekend Amanda!

Thank you, Shannon

Shannon Reyes A5256 Supply Supervisor Property Management Unit

2022. PA-005

Phoenix Police Department Desk: (602) 256-4306 shannon.reyes@phoenix.gov



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From: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Sent: Thursday, July 28, 2022 4:37 PM To: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Subject: RE: Blood Kits in stock

Thank you so much, have a great weekend!

Amanda Gallegos, M.S., D-ABFT-FT

Forensic Science Section Supervisor, Toxicology Section Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860



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From: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Sent: Thursday, July 28, 2022 4:37 PM

To: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Subject: Re: Blood Kits in stock

Hi Amanda, this week has been so busy with two audits. I appreciate your patience and apologize you have had to wait. I still have not received Lot numbers from the vendor and will have my staff

2022-PA-005

continue to reach out tomorrow. We are also looking at all the specifics of who ordered and when they were issued. I should have something to you by Monday afternoon.

Thank you, Shannon

Shannon Reyes A5256 Supply Supervisor Property Management Unit Phoenix Police Department Desk: (602) 256-4306 <u>shannon.reyes@phoenix.gov</u>



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From: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Sent: Thursday, July 28, 2022 6:54 AM To: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Subject: RE: Blood Kits in stock

You are awesome, I'm sorry this is sending you in so many directions!! Let me know if there is anything I can do to assist in the fact finding missions 😳

Amanda Gallegos, M.S., D-ABFT-FT

Forensic Science Section Supervisor, Toxicology Section Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860

2022-PA-005



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From: Shannon M Reyes <<u>Shannon.Reyes@phoenix.gov</u>> Sent: Wednesday, July 27, 2022 4:32 PM

To: Amanda B Gallegos <<u>Amanda.Gallegos@phoenix.gov</u>> Subject: Re: Blood Kits in stock

Thank you, I know your busy too!

Let me reach out to the vendor, and do a bit more research tomorrow and I will email you. I should be able to tell how many went out specifically and to what precinct and give you more details.

Thank you, Shannon

Shannon Reyes A5256 Supply Supervisor Property Management Unit Phoenix Police Department Desk: (602) 256-4306 <u>shannon.reyes@phoenix.gov</u>



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11

From: Amanda B Gallegos < Amanda.Gallegos@phoenix.gov> Sent: Wednesday, July 27, 2022 4:06 PM To: Shannon M Reyes <Shannon.Reyes@phoenix.gov> Subject: RE: Blood Kits in stock

I very much appreciate your help, I know you are very busy! Thank you again so much!

As a quick follow up, with the 101 you identified as coming back to Supply when you issued the recall, and with the number of kits we have received with that lot# in the lab we can account for about 500 of them total, so I was just curious if you received all 1,000 kits that were ordered on that PO at the same time, or if they sent you a partial order and then completed the order at a different time or with a different lot#? Just trying to figure out if there are potentially 500 additional kits out in the field that need to also be recalled.

Amanda Gallegos, M.S., D-ABFT-FT

Forensic Science Section Supervisor, Toxicology Section Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860



From: Shannon M Reyes <Shannon.Reyes@phoenix.gov>

Sent: Wednesday, July 27, 2022 2:46 PM To: Amanda B Gallegos < Amanda.Gallegos@phoenix.gov>

Subject: Re: Blood Kits in stock

Hi Amanda,

Sorry for the late response, in meetings all day. Always ask, I will help when I can.

We have reached out to Tri-tech to get Lot numbers for previous orders and I will forward that to you once I hear back. The order with lot number #67671 and was received on April 26, 2022, PO number 4400721581 and we ordered 1,000.

Hopefully I hear back today and send you an email once I do.

Thank you,

2022. PA-0305

Shannon

Shannon Reyes A5256 Supply Supervisor Property Management Unit Phoenix Police Department Desk: (602) 256-4306 shannon.reyes@phoenix.gov



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From: Amanda B Gallegos < <u>Amanda.Gallegos@phoenix.gov</u>> Sent: Tuesday, July 26, 2022 4:13 PM To: Shannon M Reyes <Shannon.Reyes@phoenix.gov> Subject: RE: Blood Kits in stock

This may be a long shot but I figured it doesn't hurt to ask 😇

When you order/receive kits do you record the number of kits received associated with the specific lot numbers? Essentially is there a way to know what date the blood kit lot #67671 was first received and how many total the department received all together?

Amanda Gallegos, M.S., D-ABFT-FT Forensic Science Section Supervisor, Toxicology Section Phoenix Police Department, Laboratory Services Bureau 621 W. Washington, Phoenix, AZ 85003 Main (602) 262-6197, Desk (602) 534-8860

2022-PA-0005

Amanda B Gallegos

From: Sent: To: Cc: Subject: Amanda B Gallegos Wednesday, August 3, 2022 10:59 AM John E Knell Benjamin S Swanholm FW: IR#s with DFE indicated - blood kit lot# 67671

FYI - List of IR#s emailed to Mark White - MCAO Vehicular Crimes Bureau Chief

Amanda Gallegos, M.S., D-ABFT-FT

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From: Amanda B Gallegos Sent: Wednesday, August 3, 2022 10:56 AM

To: whitem01@mcao.maricopa.gov Subject: IR#s with DFE indicated - blood kit lot# 67671

IR

2022-00000713532 2022-00000771106 2022-00000796400 2022-00000809109 2022-00000809423 2022-00000809500 2022-00000809746 2022-00000818681 2022-00000840503 2022-00000846635 2022-00000854699 2022-00000898983 2022-00000914044 2022-00000914945 2022-00000977240 2022-00000977575 2022-00000985772 2022-00000992102

2022-PA-JUU5

2022-00001004865 2022-00001094894

Amanda Gallegos, M.S., D-ABFT-FT

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2022-PA-5005 15

John E Knell

From:	Amanda B Gallegos
Sent:	Wednesday, August 3, 2022 11:18 AM
To:	John E Knell
Subject:	Summary of actions taken to determine source of DFE

Hey John,

Here is a quick summary of some of the actions taken to determine the source:

-Performed additional testing on the first 11 cases and determined DFE present in the tubes/eliminated analytical process as the source

-Contacted Traffic Bureau regarding van schedule/locations/phlebotomists

-Compiled information on each case (see table below); Determined only common factor was the blood kit lot# (67671)

				kit lot				
IR	date	time	Officer	#	exp date	tube lot #	batch data	Lo
2022-00000713532	5/11/2022	20:21	R. Goins #6757	67671	9/30/2023	131976	jsh051722	20
2022-00000771106	5/22/2022	5:10	Kirkland #10817	67671	9/30/2023	131976	kw052622	20
2022-00000796400	5/26/2022	21:39	R. Null #9688	67671	9/30/2023	131976	ni060222	20
2022-00000809109	5/29/2022	1:12	R. Null #9688	67671	9/30/2023	131976	ni060222	20
2022-00000809423	5/29/2022	3:20	R. Null #9688	67671	9/30/2023	131976	ni060222	20
2022-00000809500	5/29/2022	4:05	R. Null #9688	67671	9/30/2023	131976	ni060222	20
2022-00000809746	5/29/2022	11:03	Vasquez #10939	67671	9/30/2023	131976	ni060222	62
2022-00000818681	5/31/2022	0:02	Price #7704	67671	9/30/2023	131976	djs060722	22
2022-00000840503	6/3/2022	23:53	R. Null #9688	67671	9/30/2023	returned	djs060922	30
2022-00000846635	6/5/2022	5:58	R. Null #9688	67671	9/30/2023	returned	djs060922	30
2022-00000854699	6/6/2022	19:19	D. Deakyne #10741	67671	9/30/2023	returned	djs060922	18
2022-00000898983	6/15/2022	1:49	McGillis #5599	67671	9/30/2023	returned	gms062222	21
2022-00000914044	6/17/2022	22:22	R. Null #9688	67671	9/30/2023	returned	gms062222	30
2022-00000914945	6/18/2022	22:30	Aguirre #10443	67671	9/30/2023	131976	gms062222	62
2022-00000977240	6/30/2022	0:39	Souza #11010	67671	9/30/2023	131976	kw070522	M
2022-00000977575	6/30/2022	4:35	Souza #11010	67671	9/30/2023	131976	kw070522	M
2022-00000985772	7/1/2022	16:26	Martinez #10387	67671	9/30/2023	131976	kw070722	M
2022-00000992102	7/2/2022	20:15	Martinez #10387	67671	9/30/2023	131976	kw070722	M
2022-00001004865	7/5/2022	6:43	Aguirre #10443	67671	9/30/2023	131976	rb070822	19
2022-00001094894	7/22/2022	5:43	Vasquez #10939	67671	9/30/2023	131976	gms072622	Es

-Reached out to other laboratories to inquire about other potential occurrences (LVMPD was only response that indicated similar increase in presence of DFE, they were also unable to determine the source)

-Contacted Tritech, as of this date only response received is the following: I have sent an inquiry into our plant for feedback/comment. I do know our tubes are evacuated (e.g. have a vacuum) on the ID to draw the blood into the tube, so the presence of a "gas" should not be present. To prove it came from the tube, they would have to test the tubes by themselves with no blood. Otherwise their devices used to draw blood or testing/cleaning practices could be contaminating the specimen. I will follow up more when I have feedback from our manufacturing plant.

2022-PA-0005

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