

Borgfeld, Lynette

From: Vela, Norma C
Sent: Thursday, August 14, 2008 10:07 AM
To: Vela, Norma C; Borgfeld, Lynette; Tanksley, Susan; Hutcheson, Eldridge
Cc: Berrios, Nora
Subject: RE: Request for random neonatal dried blood spots

I spoke with the Billing Branch and explained the situation. They way we'll handle it is basically as laid out in Scenario #2 from my 7/25 email down below.

They can set up a billing account WITHOUT a submitter number being assigned, since in this case there will be no testing ordered through the usual lab form process.

- To set up this billing account they will need the entity name, entity billing address and a contact person/number for payment issues.
- Working with the Billing Branch, you'll need to request a procedure code for this service (you can call it "neonatal dried blood spot" or "NBS Special Handling Fee") and you'll need to develop a price.
- Then either on a monthly or quarterly basis (whatever you think best and/or work out with Avioq), someone from NBS will need to notify the Billing Branch of the quantity of blood spots to bill for and the date range associated with the charge to be billed. They will basically handle it like a manual charge entry.

That's it. No contract or PO needed.

-norma

From: Vela, Norma C
Sent: Friday, August 08, 2008 9:12 AM
To: Borgfeld, Lynette; Tanksley, Susan; Hutcheson, Eldridge
Cc: Berrios, Nora
Subject: RE: Request for random neonatal dried blood spots

Jennifer has been out this week – I will ask her on Monday and will let you know whether or not Avioq will need a submitter number. That process does not take a long time and is a simple form they will complete with Sandra Navarro.

As for the other questions, that would be your call.

From: Borgfeld, Lynette
Sent: Friday, August 08, 2008 9:08 AM
To: Tanksley, Susan; Vela, Norma C; Hutcheson, Eldridge
Cc: Berrios, Nora
Subject: RE: Request for random neonatal dried blood spots

Just FYI,
We charge MD Anderson \$3.10 for the Hemoglobinopathy results (not the dried blood spots).
We charge PE a \$2 equivalent for anonymous dried blood spots with no attached demographic information.

Norma, have you talked with the billing branch?
How is the entry of this charge to the billing system done?

Has anyone been in contact with Avioq?

Do we need to have a meeting? If so, who do we need to invite?

Thanks,
Lynette

9/18/2008

From: Tanksley, Susan
Sent: Thursday, August 07, 2008 6:41 PM
To: Vela, Norma C; Hutcheson, Eldridge; Borgfeld, Lynette
Cc: Berrios, Nora
Subject: RE: Request for random neonatal dried blood spots

Hi,

Just following up on this issue. We haven't done anything with this request yet. Due to current procedures for use of NBS dried blood spots, we'd also need the requestor to submit a request through the IRB (for exemption). Can someone follow up while I am out?

Thanks,

Susan M. Tanksley, Ph.D.
Biochemistry and Genetics Branch Manager
Texas Department of State Health Services
(512) 458-7111 x 3106

From: Vela, Norma C
Sent: Friday, July 25, 2008 4:02 PM
To: Hutcheson, Eldridge; Tanksley, Susan
Cc: Neill, Susan; Granado, Anabel; Berrios, Nora; Vela, Norma C
Subject: RE: Request for random neonatal dried blood spots

Susan T – I suggest a price of at least \$ 3.10 since that is the price that we sell the blood spots to MD Anderson for.

I'm going to ask Jennifer/Billing Branch if they require an entity to have a submitter number in order to set up a billing account. Depending on what she says, we'll:

Scenario #1-

1. Secure a submitter number through Sandra Navarro (we'll request expedited process) for Avioq and use that submitter number to set up a billing account.
2. NBS determines the price and create a new internal procedure number for this service – let's call it "NBS Special Handling Fee" and we'll get that signed/approved by Sherry Clay.
3. I'll let the billing branch folks know that we'll handle the entry of this charge to the billing system manually – i.e., NBS will call billing branch when this is done, so the charge can be entered into the system and a bill can be generated out of the billing system.

Scenario #2-

1. Billing account for Avioq set up without submitter number.
2. NBS determines the price and creates a new internal procedure number for this service – let's call it "NBS Special Handling Fee" and we'll get that signed/approved by Sherry Clay.
3. I'll let the billing branch folks know that we'll handle the entry of this charge to the billing system manually – i.e., NBS will call billing branch when this is done, so the charge can be entered into the system and a bill can be generated out of the billing system.

This way we avoid contracts and po's. Let's talk next week. –norma x6626

From: Hutcheson, Eldridge
Sent: Friday, July 25, 2008 3:50 PM
To: Tanksley, Susan

9/18/2008

Cc: Neill, Susan; Delamater, Elizabeth; Granado, Anabel; Raj, Pushker; Vela, Norma C
Subject: RE: Request for random neonatal dried blood spots

Susan,

Please coordinate with Norma on how to bill for these 600 dbs. Dr. Neill suggests billing under our fee schedule as handling fees, like \$5.00 each, but at least \$3.00 each. After a billing method is determined, call him at 919-477-8354
Cell 919-225-7368
and work out the details. He told Dr. Neill that he was on a short timeline for the dbs.

Thanks,
Hutch

From: Raj, Pushker
Sent: Friday, July 25, 2008 10:21 AM
To: 'Cham Chetty'
Cc: Delamater, Elizabeth; Tanksley, Susan; Granado, Anabel; Hutcheson, Eldridge
Subject: RE: Request for random neonatal dried blood spots

We do not test neonates DBS in HIV/STD lab. I am forwarding to the Newborn Screening Group. Someone will contact you and let you know if 600 DBS can be shipped to you.

Pushker Raj, Ph.D.
Manager
Molecular & Serological Analysis Group
Laboratory Services Section
Texas Department of State Health Services
Tel: 512-458-7760
Fax: 512-458-7452

From: Cham Chetty [mailto:chettyc@avioq.com]
Sent: Friday, July 25, 2008 9:46 AM
To: Raj, Pushker
Cc: jvm0@cdc.gov
Subject: Request for random neonatal dried blood spots

Dear Mr. Pushker,

I am the CEO of Avioq, Inc, a startup company that recently acquired the Vironostika HIV-1 assay from bioMerieux (BMX). I worked for BMX for almost 20 years and was R&D director overseeing all of the HIV and HTLV assays when I retired 2 years ago.

Our new company is in the process of validating the Vironostika HIV assay with all three sample claims, serum/plasma, DBS, and oral fluid, at our contract manufacturing site (FDA approved facility). As part of these validation activities, we have to test our kits with random neonate DBS. In the past, BMX obtained these samples from Texas DOH by signing an agreement with certain terms and conditions. We are prepared to do the same once we have our regular production in place.

For now, is it possible to obtain about 600 random neonatal dried blood spots in the next two weeks under a one time agreement so we can initiate our validation studies? I spoke to Joanne Mai of CDC and she recommended that I should contact you first for these samples.

Thank you in advance for your help.
Regards,

Chamroen Chetty, Ph.D.
CEO
Avioq, Inc.

9/18/2008

Borgfeld, Lynette

From: Vela, Norma C
Sent: Tuesday, August 26, 2008 5:29 PM
To: Hutcheson, Eldridge; Borgfeld, Lynette; Reilly, Brendan
Cc: Vela, Norma C
Subject: RE: letter to request de-identified random neonatal DBS

I believe so. This situation is kinda like a contract situation for the sale of laboratory services, except in this case there is no contract in place and we're not selling any testing.

Double check with Rachael to see how this should best be allocated (008 contract funding or 164 public health fees). What I'm looking for is this: which pot of money will it benefit us to book this under. Once she says which one, I'll work with the Billing Branch to tell them how to set it up so that it does get to that desired bucket.

Oh, Lynette – as for terms and conditions, here's some to consider:

- Mention that they are to pay for the dried blood spots at a cost of (fill in blank) for each specimen provided in addition to the cost of the shipping
- Identify the means by which they will make their request known to us (since it appears this will happen more than once).
- Identify the turn around time (if any needed) between their request and our response.
- Try to identify the general termination of this agreement/situation – this can't go on forever, at some point, we'd need to raise prices, etc..
- Identify clearly the contact person for billing issues, the information for billing (where the bill will go), the person or contact for the samples (who will receive, etc.)
- Anything you think is prudent to address IRB (I'm clueless about such things and happily so).

That's really all I can think of right now. I'm going to be out beginning tomorrow through Tuesday 9/2, so we can talk more then if needed. -n

From: Hutcheson, Eldridge
Sent: Tuesday, August 26, 2008 5:12 PM
To: Borgfeld, Lynette; Vela, Norma C; Reilly, Brendan
Subject: RE: letter to request de-identified random neonatal DBS

I suggest a handling fee of \$4.00 / specimen with the shipping paid by the requestor.

Norma, can we use the handling fee and have the funds available for lab use?

Hutch

From: Borgfeld, Lynette
Sent: Tuesday, August 26, 2008 4:29 PM
To: Hutcheson, Eldridge; Vela, Norma C; Reilly, Brendan
Subject: FW: letter to request de-identified random neonatal DBS

Hutch,
Attached is a request for 600 DBS. In the letter it states "600 every two months"... this is the first I had heard of an "on-going" request. I can verify that with him – however, I also need to provide him with "the terms and conditions", which I assume means the cost and billing processes. Have you and Dr. Neill set a fee for this service? I have attached a previous email that shows base line estimates for the work required.

Norma,
What do you suggest we use as "the terms and conditions"

8/27/2008

Brendan,

What thoughts do you have on providing 600 DBS (less than 2 wks from DOC) every two months?

All,

He still needs to submit IRB documents for approval.

Thanks,

Lynette

(512)458-7318 ext.2471

lynette.borgfeld@dshs.state.tx.us

From: Cham Chetty [mailto:chettyc@avioq.com]

Sent: Tuesday, August 26, 2008 1:07 PM

To: Borgfeld, Lynette

Subject: letter to request de-identified random neonatal DBS

Dear Ms Borgfeld,

Per your request, see attached for a letter to request de-identified random neonatal DBS samples for use as part of a QC release of the Vironostika HIV-1 Plus O assay that we are licensing from BioMerieux for manufacturing and distribution. Once we have completed the validation process, the name of the assay will be changed. We will update you when the change is implemented. I will also contact your IRB as you requested. Please let me know if this letter contains all of the information that you need.

Regards,

Cham

8/27/2008