April 17, 2006

Stratus® CS STAT Fluorometric Analyzer Field Correction Addendum

Catalog No.	Description	Catalog No.	Description
CBHCG	BHCG TestPak	CBHCG-D	BHCG DilPak
CCKMB	CKMB TestPak	CCKMB-D	CKMB DilPak
CCTNI	Acute Care™ cTnI TestPak	CCTNI-D	cTnI DilPak
CDDMR	DDMR TestPak	CDDMR-D	DDMR DilPak
CMYO	MYO TestPak	CMYO-D	MYO DilPak
CPBNP	Acute Care™ pBNP TestPak	CPBNP-D	Acute Care™ pBNP DilPak

Dear Dade Behring Customer:

Our records indicate that your facility uses the Stratus® CS STAT Fluorometric Analyzer.

On April 3, 2006, Dade Behring issued a field correction letter informing customers of a very low-frequency issue that may result in the reporting of erroneous test results without an associated error code when processing paks greater than two months from the date of manufacture. At that time, preliminary investigation demonstrated that the foil sealing the Stratus® CS TestPaks and DilPaks may occlude the pipet tip, resulting in insufficient aspiration of fluids. Test results may be falsely elevated or depressed, and the magnitude of the inaccuracy may vary based on the degree of occlusion.

We have since confirmed one customer report that indicates this very low-frequency issue may not be isolated to TestPaks and DilPaks greater than two months old. Based on this new information, and **until further notice, we are instructing Stratus® CS customers to process all samples and dilutions in duplicate**.

You have our assurance that we continue to work diligently to identify the root cause and will implement an appropriate solution. Currently there are two potential solutions under investigation; an instrument error code to flag the presence of an occlusion, and a new lot of foil that will initiate in production this month. The effectiveness of these potential solutions is being assessed. We will provide you with regular updates to assist you in managing your Stratus® CS testing.

Protection against the very low-frequency occlusions can be provided by following these steps:

Step 1. Check the lot numbers of the Stratus® CS TestPaks and DilPaks in your facility's inventory.

Step 2. Compare product lot numbers with the listings in Table 1 and Table 2 (enclosed).

Step 3. If you have product lot numbers listed in Table 1, please do the following:
a) Discontinue using any Stratus® CS Pak lots listed in Table 1.
b) Discard any remaining inventory of these lots.
c) Please contact your local Dade Behring Customer Service Center at 800-241-0420 to report your replacement needs, and the Customer Service team will advise you of replacement product availability.

Step 4. For product lot numbers listed in Table 2, please do the following:
a) Note the revised expiration date and use this new date to determine when to discontinue use of these lots.
b) Once the revised expiration date occurs, discontinue use of the lot.
c) Please contact your local Dade Behring Customer Service Center at 800-241-0420 to report your replacement needs for any product not used prior to the new expiration date.

Caution: Please pay close attention to the revised expiration date as the Stratus® CS STAT Fluorometric Analyzer will not flag the lot as being expired. The operator will need to ensure use of the product within the revised expiration date provided in Table 2.

ADDITIONAL INSTRUCTIONS:

Step 5. Process all samples and dilutions in duplicate. (Please see Attachment 1 – Recommendations for Processing Duplicates)

For test results that fall above the assay range, if DilPaks are not available, samples may be manually diluted as described in the TestPak insert sheet, or test results may be reported as greater than the assay range for that method. Because foil is also used to seal Stratus® CS CalPaks, the potential exists for occlusion of the pipet tip during CalPak puncture; however, a calibration error code will be generated if this situation occurs.

As recommended in the product insert sheets, test results should be interpreted in conjunction with the patients' medical history, clinical presentation, and other findings. We ask that you review the content of this letter with your laboratory director to assess your laboratory's need for review of previously reported test results.

Effective April 3, 2006, all Stratus® CS TestPaks and DilPaks are labeled with the shortened expiration dates, with maximum dating of 2 months. During this transition, please take into

account both the shortened dating and requirement for duplicate testing when placing orders. We also ask that you please forward this notification to anyone to whom you may have distributed Stratus® CS products.

We apologize for any inconvenience this situation has caused and thank you for your support. If you have any questions regarding this information, please contact your local Dade Behring Technical Assistance Center at 800-405-6473 for additional support.

Sincerely,

[redacted]
Product Group Manager, Global Marketing
Dade Behring, Inc.

Table 1 – Discontinue Use of the Following Lots

Method	TestPak Lots				DilPak Lots	
	Date of Manufacture	Lot Number	Date of Manufacture	Lot Number	Date of Manufacture	Lot Number
CTNI	2005-10-03	235276002	2005-12-12	235346002	2005-11-28	835332002
	2005-10-09	235283002	2005-12-19	235353002	2006-02-13	836044002
	2005-10-17	235290002	2005-12-27	235361002		
	2005-10-24	235297002	2006-01-09	236009002		
	2005-10-31	235304002	2006-01-16	236016002		
	2005-11-07	235311002	2006-01-23	236023002		
	2005-11-14	235318002	2006-01-30	236030002		
	2005-11-21	235325002	2006-02-06	236037002		
	2005-12-04	235338002	2006-02-13	236044002		
	2005-12-05	235339002				
CKMB	2005-10-03	245276002	2006-02-06	246037002	2005-10-31	845304002
	2005-10-16	245289002				
	2005-10-31	245304002				
	2005-11-14	245318002				
	2005-11-28	245332002				
	2005-12-27	245361002				
	2006-01-23	246023002				
MYO	2005-10-10	515283002	2006-02-13	516044002	2006-01-23	816023002
	2005-11-07	515311002				
	2005-11-28	515332002				
	2005-12-05	515339002				
	2006-01-03	516003002				
	2006-01-16	516016002				
PBNP	2005-10-03	215276002				None
	2005-11-07	215311002				Affected
	2005-11-28	215332002				
	2006-01-30	216030002				
DDMR	2005-10-24	405297002			2005-10-10	805283002
	2005-12-12	405346002			2005-12-12	805346002
	2006-01-03	406003002			2006-02-13	806044002
	2005-01-30	406030002				
BHCG	2006-01-03	446003002			2005-10-24	945297002
					2005-11-28	945332002
					2006-01-11	946011002
					2006-02-13	946044002

Table 2 – New Expiration Dates for Lots

Method	TestPaks			DilPaks*		
	Date of Manufacture	Lot Number	Revised Expiration Date	Date of Manufacture	Lot Number	Revised Expiration Date
CTNI	2006-02-20	236051002	2006-04-20		N/A	N/A
	2006-02-27	236058002	2006-04-27			
	2006-03-06	236065002	2006-05-06			
	2006-03-17	236072002	2006-05-17			
	2006-03-24	236079002	2006-05-24			
CKMB	2006-02-20	246051002	2006-04-20	2006-02-27	846058002	2006-04-27
	2006-03-06	246065002	2006-05-06			
	2006-03-20	246079002	2006-05-20			
MYO	2006-02-27	516058002	2006-04-27		N/A	N/A
	2006-03-13	516072002	2006-05-13			
PBNP	2006-03-06	216065002	2006-05-06	2006-03-06	916065002	2006-05-06
DDMR	2006-03-20	406079002	2006-05-20		N/A	N/A
BHCG	2006-02-27	446058002	2006-04-27		N/A	N/A

*For test results that fall above the assay range, if DilPaks are not available, follow the instructions in the TestPak insert sheet or report test results as greater than the assay range for that method.

Attachment 1 – Recommendations for Processing Duplicates

1. Ensure that the **Retrieve Sample** and **Rotor Hold** options are ON and **Timeout** is set to 30 Minutes (refer to "Rotor Usage" in Section 7-14 of your Stratus® CS Operator's Guide, attached). These settings will allow the sample cup or rotor to be retrieved rather than placing them in the waste container.
2. For each patient sample, review the request to determine the number of tests (including duplicates) to be processed.
3. Ensure that you have enough plasma to process all the requested tests (refer to table below).
4. Place up to 4 TestPaks into the pak manager.
5. Process tests.
6. If more than 4 tests are required for a single sample, the additional tests must be processed from either a sample cup or a second sample tube, as follows:
    a. **Sample cup:** Transfer plasma from the rotor or externally centrifuged sample tube into a sample cup (refer to "Loading and Processing a Sample Cup" in Section 3-24 of your Stratus® CS Operator's Guide, attached).
    b. **Second sample tube:** Follow normal procedures for processing a sample tube (refer to "Loading and Processing a Sample Tube" in Section 3-15 of your Stratus® CS Operator's Guide, attached).
7. Repeat Steps 4 through 6 until all desired testing is complete.

Example:

- CTNI, CKMB, and MYO are requested (3 tests).
- All tests must be processed in duplicate, for a total of 6 tests.
- 800 µL of plasma is required to process 6 tests.
- The first 4 tests (CTNI and CKMB, in duplicate) may be processed from either a sample tube using a rotor, or a sample cup using plasma from an externally centrifuged tube.
- The additional 2 tests (MYO, in duplicate) must be processed from either a sample cup, or a second sample tube using a rotor.

Sample Needs Table:

Number of Tests per Sample	Total Plasma Volume Required		Sampling Mode*
	µL	cc	
1	200	0.2	Sample Tube (Rotor) or Sample Cup
2	300	0.3	
3	400	0.4	
4	500	0.5	
5	700	0.7	Sample Cup or Second Sample Tube
6	800	0.8	
7	900	0.9	
8	1000	1.0	
9	1200	1.2	Sample Cup or Third Sample Tube
10	1300	1.3	
11	1400	1.4	
12	1500	1.5	

* A maximum of 4 tests can be processed from a single sample cup or rotor.