

To: 'arosendorff@
From: Adam Rosendorff
Sent: Mon 10/20/2014 11:35:37 PM
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Subject: FW: Changes in primary methods and CMS reporting
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From: Adam Rosendorff
Sent: Thursday, October 16, 2014 3:40 PM
To: Brad Arington
Cc: Daniel Young
Subject: Changes in primary methods and CMS reporting

Brad

I would like to de-enroll in CMS reporting for the following analytes based on the fact that they are no longer run on methods for which there is a peer-group (Theranos LDT methods), and based on the fact that they are no longer run on predicate methods primarily.

Up till now, proficiency has been run via CAP and API for the predicate methods only, and reported to CMS as our primary method. Since the predicate methods are no longer our primary methods (42 CFR 493 §801 Subpart 6), and since commercial PT is not available, proficiency will be replaced by AAP (in-house). To be clear we will still perform proficiency testing for our predicate methods, however they will not be reported to CMS if they are not the primary methods. The latter group consists mainly of immunoassays. To summarize the list below is the intersection of the following sets: (a) Theranos methods that are primary and (b) Methods that are reportable to CMS.

The Theranos methods that should be de-enrolled as the CMS-reportable methods are:

ALT
Alkaline Phosphotase
Amylase
AST
Bilirubin
Calcium
Chloride
Cholesterol-total
Cholesterol-HDL
CO2
Creatine Kinase
Creatinine
Gamma GT
Glucose (Plasma)
Iron Total
LDH,
Magnesium,
Potassium,
Sodium,
Total Protein,
Triglycerides,
Urea Nitrogen
Uric Acid

Edison assays

TSH
FT4
HCG
TT4
TT3

Hematology

CBC/Diff

Thanks,

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