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Letter to Editor

Biochemistry Section

An Unrecorded Pre-Pre-Analytical Error in Serum Iron Analysis

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Evidence based laboratory medicine is widely used in clinical practice. Laboratory results are very important in the decision making of patient treatment. Medical tests impact patient health by influencing clinical management decisions on what treatment options are selected [1]. Proper blood collection and timely processing are critical pre-analytical steps needed for the integrity of lab results for any analyte [2]. It has been reported that the pre-analytical phase is error-prone, only recently has it been demonstrated that most errors occur in the 'pre-pre-analytical phase'. This comprises the initial procedures of the testing process performed by healthcare personnel outside the laboratory walls and outside the direct control of the clinical laboratory [3].

Iron Deficiency Anaemia is endemic in India, so this investigation becomes imperative for its diagnosis [4]. The various pre-analytical factors that affect the estimation of serum iron measurements are as Gender, Menstrual cycle, Lipaemia, Needles.

Needles used with evacuated tubes, syringes, catheters and butterfly systems are composed of various materials including stainless steel, aluminum, titanium, chromium, iron, manganese, nickel and alloy of these metals. Typically needles have a long sharp end. Needle components (eg chromium, iron, manganese and nickel) can contaminate blood specimens and interfere with subsequent chemical reactions or falsely elevate blood metal levels [5].

A case reported in our laboratory (National Accreditation Board for testing and calibration Laboratories, International organization for Standardization (NABL ISO) 15189 accredited) showed a variation of serum iron samples. The first sample collected from an Iron Deficiency Anaemia female patient of age 35 years showed very high serum iron levels. A history of blood transfusion a day prior to sample collection was given by the patient.

Patient's history of menstrual bleeding was taken which revealed no positive history. History of ingestion of oral contraceptives, Iron-dextran administration, and ingestion of iron (including iron-fortified vitamins or supplements) was taken which was negative. These factors are important as they elevate serum iron values. The next thing done was checking for any Lipaemia in the patients sample as plasma concentration of serum iron is affected by it but the serum sample was absolutely clear.

The serum iron levels were done by the ferrozine dye timed end point method [6] in DXC 800 auto analyser and the value came to be 250 µg/dl (The normal value of Serum Iron: 41-132 µg/dl.) The result did not match with the clinical history of the patient. The sample was rerun to cross check the results a similar result (245 µg/dl) was obtained again. Then a fresh sample was taken from the patient and run which showed a low value of 38µg/dl. The second sample value matched with the patients peripheral smear report of microcytic hypochromic anaemia.

A root cause analysis was undertaken for the first erroneous result. As sitting in a NABL accredited laboratory the chance of error has to be zero so as to achieve the six sigma status. Applications person of DXC 800 autoanalyser was called to rule out the possibility of any random error. All the checks were undertaken and the machine was found to be in order.

After ruling out all the possibilities of causes of erroneous results we pinpointed that the cause of these two different reports was contamination of the sample taken for serum iron analysis was with the iron component of the needle used for sample collection.

RECOMMENDATIONS

Diagnostic services are becoming even more numerous and more sophisticated. The physician's dependency on these methods is so great that occasionally the basic clinical approach to the patient seems to become secondary.

Blood collection devices should achieve the intended performance levels during defined conditions of use, so we recommend that–

(1) When interference is suspected as laboratory personnel we should test the same analyte with the alternative method.

(2) Contact the collection device assay manufacturer. If applicable file a medical device alert to appropriate regulatory organization. If possible change the manufacturer.

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