Release Of Results

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QUALITY

Three step Measures for ensuring highest standard of quality

- Quality Assurance
  - assessing performance in all steps of the laboratory testing cycle
- Quality Control
  - aggregate of processes and techniques to detect, reduce, and correct deficiencies in an analytical process
- Quality Improvement
  - continuously assessing and adjusting performance using statistically and scientifically accepted procedures

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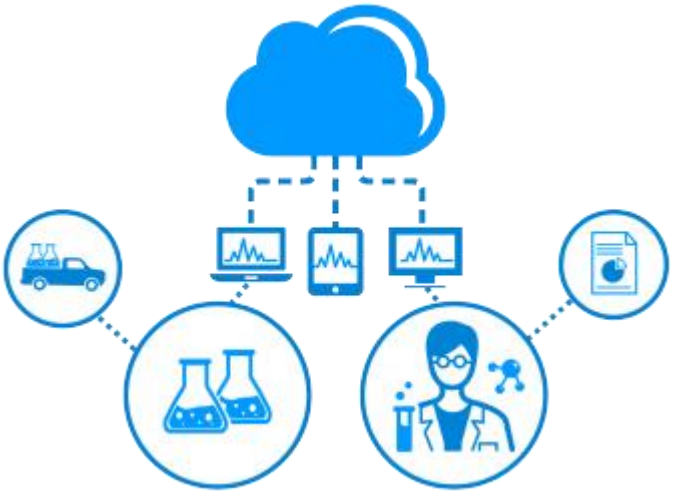
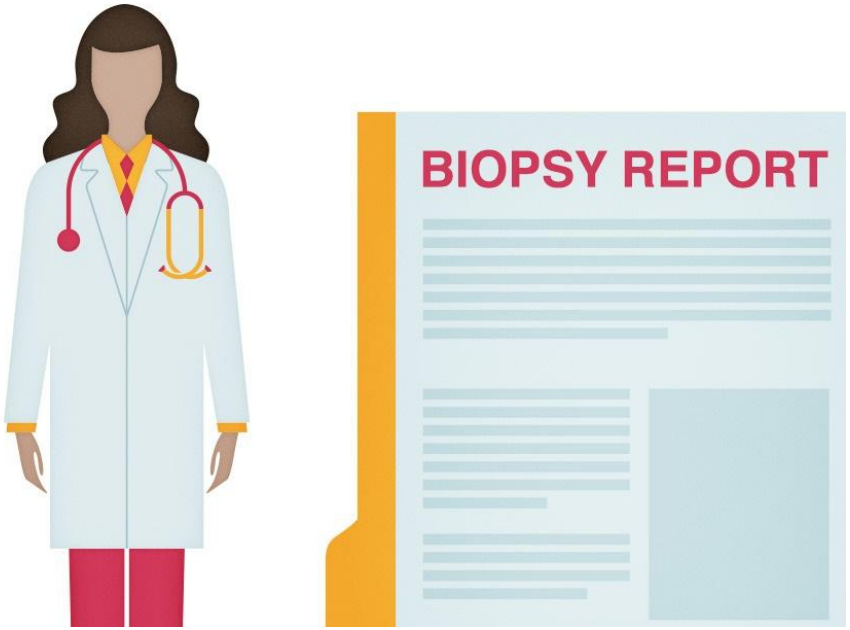
Post-examination Processes



Reporting of results



General

- The results of each examination shall be reported accurately, clearly, unambiguously and in accordance with any specific instructions in the **examination procedures**.
- The laboratory shall define the format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory. **The laboratory shall have a procedure to ensure the correctness of transcription of laboratory results**.
- Reports shall include the **information necessary** for the **interpretation** of the examination results.
- The laboratory shall have a **process** for **notifying** the requester when an examination is **delayed** that could compromise patient care.

Report content

The report shall include, but not be limited to, the following:

a) a clear, unambiguous identification of the examination including, where appropriate, the **examination procedure**;

b) the **identification of the laboratory** that issued the report;

c) identification of all **examination**s that have been performed by a **referral laboratory;**

d) **patient identification** and **patient location** on each page;

e) name or other **unique identifier of the requester** and the requester's **contact details**;

f) **date of primary sample collection** (and time, when available and relevant to patient care);

Report content

g) t**ype** of primary sample;

h) measurement procedure, where appropriate;

i) examination results reported **in SI units**, units traceable to SI units, or other applicable units;

j) **biological reference intervals**, clinical decision values, or diagrams/homograms supporting clinical decision values, where applicable;

NOTE Under some circumstances, it might be appropriate to distribute lists or tables of biological reference intervals to all users of laboratory services at sites where reports are received.

k) interpretation of results, where appropriate;

- NOTE Complete interpretation of results requires the context of clinical information that may not be available to the laboratory.

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Report content

l) other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure);

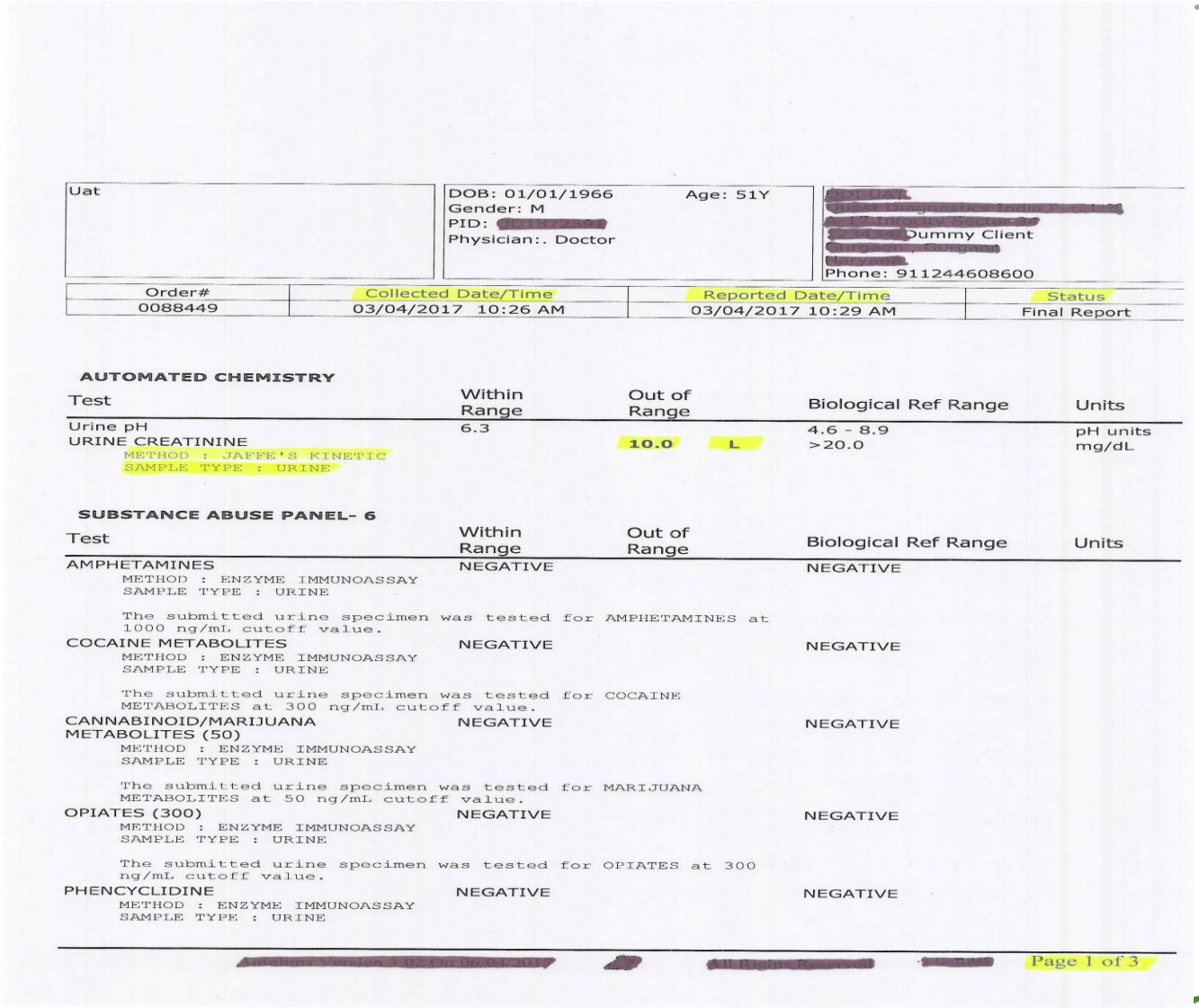
m) identification of examinations undertaken as part of a research or development programm and for which no specific claims on measurement performance are available;

n) **identification of the person(s) reviewing the results** and authorizing the release of the report (if not contained in the report, readily available when needed);

o) **date of the report, and time of release** (if not contained in the report, readily available when needed);

p) **page number to total number of pages** (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.).

Sample Report



Uat	DOB: 01/01/1966 Age: 51Y Gender: M PID: [redacted] Physician:. Doctor	[redacted] Dummy Client Phone: 911244608600

Order#	Collected Date/Time	Reported Date/Time	Status
0088449	03/04/2017 10:26 AM	03/04/2017 10:29 AM	Final Report

AUTOMATED CHEMISTRY

Test	Within Range	Out of Range	Biological Ref Range	Units
Urine pH	6.3		4.6 - 8.9	pH units
URINE CREATININE		10.0 L	>20.0	mg/dL
METHOD : JAFFE'S KINETIC				
SAMPLE TYPE : URINE				

SUBSTANCE ABUSE PANEL- 6

Test	Within Range	Out of Range	Biological Ref Range	Units
AMPHETAMINES	NEGATIVE		NEGATIVE	
METHOD : ENZYME IMMUNOASSAY				
SAMPLE TYPE : URINE				
The submitted urine specimen was tested for AMPHETAMINES at 1000 ng/mL cutoff value.				
COCAINE METABOLITES	NEGATIVE		NEGATIVE	
METHOD : ENZYME IMMUNOASSAY				
SAMPLE TYPE : URINE				
The submitted urine specimen was tested for COCAINE METABOLITES at 300 ng/mL cutoff value.				
CANNABINOID/MARIJUANA METABOLITES (50)	NEGATIVE		NEGATIVE	
METHOD : ENZYME IMMUNOASSAY				
SAMPLE TYPE : URINE				
The submitted urine specimen was tested for MARIJUANA METABOLITES at 50 ng/mL cutoff value.				
OPIATES (300)	NEGATIVE		NEGATIVE	
METHOD : ENZYME IMMUNOASSAY				
SAMPLE TYPE : URINE				
The submitted urine specimen was tested for OPIATES at 300 ng/mL cutoff value.				
PHENCYCLIDINE	NEGATIVE		NEGATIVE	
METHOD : ENZYME IMMUNOASSAY				
SAMPLE TYPE : URINE				

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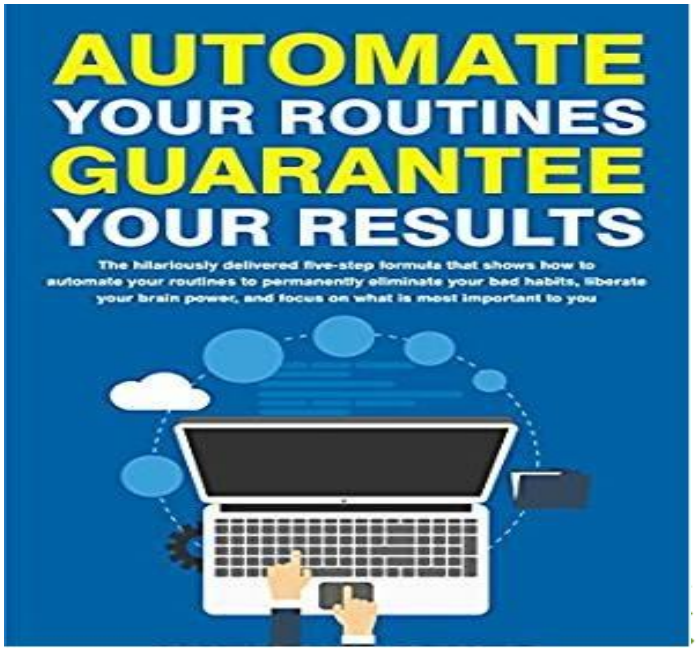
Release of Results



Review of results

- The laboratory shall have procedures to ensure that **authorized personnel** review the results of examinations before release and evaluate them against **internal quality control** and, as appropriate, **available clinical information** and **previous examination results**.

- When the procedure for reviewing results involves **automatic selection** and reporting, **review criteria shall be established**, approved and documented

- For establishing these criteria the authorized person shall make use of available standards (e.g., CLSI Auto 10) or Guidelines (e.g., ICSH for haematology - Laboratory Hematology 2005; 11:83-90. The International Consensus Group for Hematology Review: Suggested Criteria for Action Following Automated CBC and WBC Differential Analysis).

Report attributes

The laboratory shall ensure that the following report attributes effectively communicate laboratory results and meet the users' needs:

a) comments on **sample quality** that might compromise examination results;

b) comments regarding sample suitability with respect to **acceptance/rejection criteria;**

c) **critical results**, where applicable;

d) **interpretive comments** on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report

General

The laboratory shall establish documented procedures for the release of examination results, including details of **who may release results** and to whom. The procedures shall ensure that the following conditions are met.

- When the quality of the **primary sample received is unsuitable for examination**, or could have compromised the result, this is indicated in the report.
- When examination results fall within established **“alert” or “critical” intervals**:

— **a physician** (or other authorized health professional) **is notified immediately** [this includes results received on samples sent to referral laboratories for examination;

— **records are maintained** of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications.

c) **Results are legible,** without mistakes in transcription, and reported to persons authorized to receive and use the information.

General

d) When results are transmitted as **an interim report**, **the final report** is always forwarded to the requester.

e) There are **processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients**. Results provided orally shall be followed by a written report. There shall be a record of all oral results provided.

- NOTE 1 For the results of some examinations (e.g. certain genetic or infectious disease examinations) special counselling may be needed. The laboratory should endeavour to see that results with serious implications are not communicated directly to the patient without the opportunity for adequate counselling.

- NOTE 2 Results of laboratory examinations that have been separated from all patient identification may be used for such purposes as epidemiology, demography or other statistical analyses.

Computer Nonsense Metrics

$$\frac{[\text{urine culture}] * [\text{glucose}] * [\text{INR}]}{[\text{NUPA}_{\text{hr}}] * [\text{Telephone}_{\text{minutes}}]} \text{X100}$$

Just because a computer can calculate a value, doesn't mean that it should.

Automated Selection & Reporting of Results

If the laboratory implements a system for **automated selection** and **reporting of results**, it shall establish a documented procedure to ensure that:

a) the **criteria for automated selection and reporting are defined, approved, readily available and understood by the staff**;

NOTE Items for consideration when implementing automated selection and reporting include changes from previous patient values that require review and values that require intervention by laboratory personnel, such as absurd, unlikely or critical values.

b) **the criteria are validated** for proper functioning before use and verified after changes to the system that

might affect their functioning;

c) **there is a process for indicating the presence of sample interferences** (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination;

Automated Selection & Reporting of Results

d) there is a **process for incorporating analytical warning messages** from the instruments into the automated selection and reporting criteria, when appropriate;

e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection;

f) there is a process for rapid suspension of automated selection and reporting.

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Revised reports

When an original report is revised there shall be written instructions regarding the revision so that:

a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report;

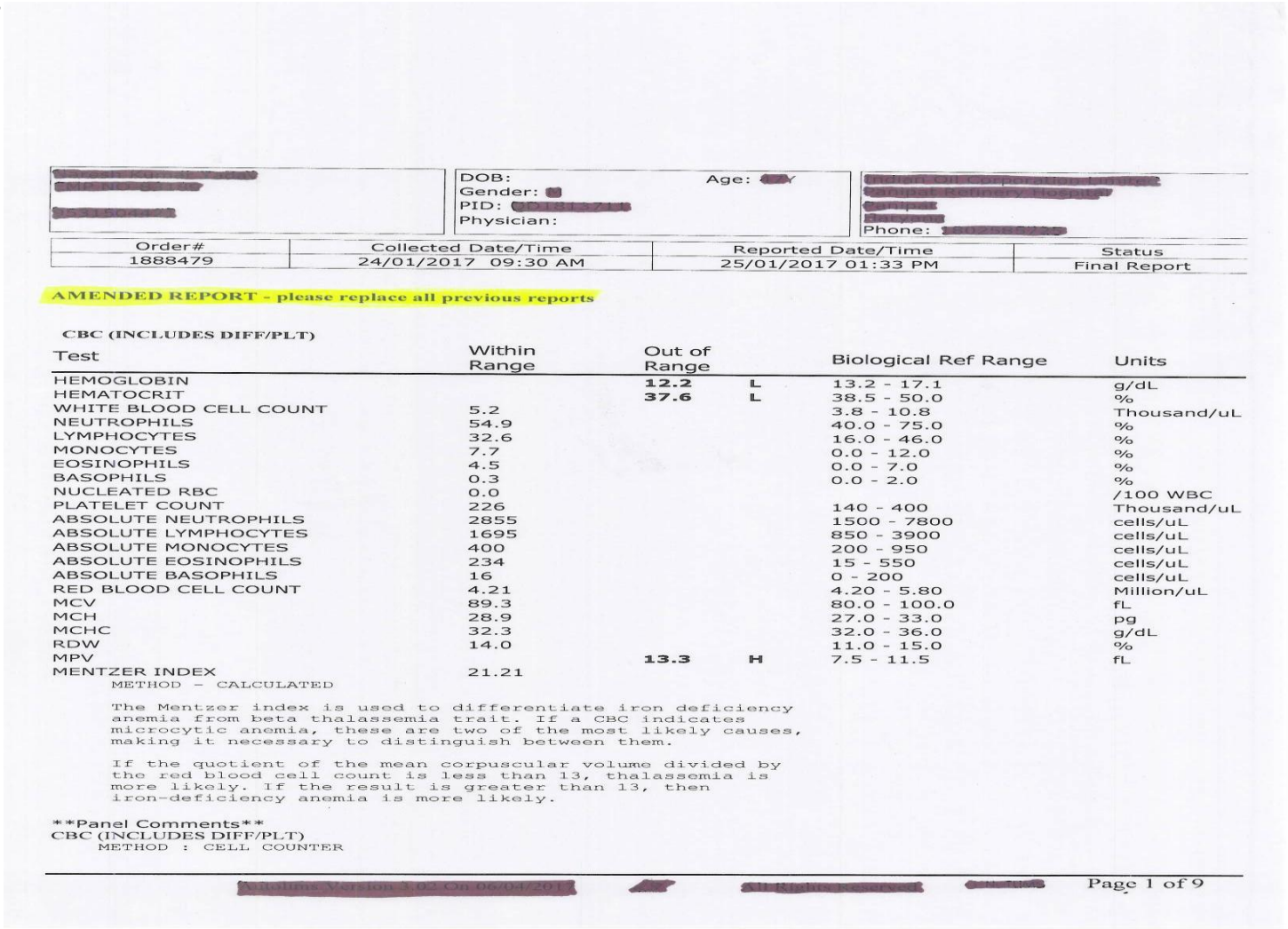
b) the user is made aware of the revision;

c) the revised record shows the time and date of the change and the name of the person responsible for the change;

d) the original report entries remain in the record when revisions are made.

- Results that have been made available for clinical decision making and revised shall be retained in subsequent cumulative reports and clearly identified as having been revised.
- When the reporting system cannot capture amendments, changes or alterations, a record of such shall be kept.

Sample Report



[redacted]

DOB:
Age: [redacted]
Gender: [redacted]
PID: [redacted]
Physician:

[redacted]
Phone: [redacted]

Order#	Collected Date/Time	Reported Date/Time	Status
1888479	24/01/2017 09:30 AM	25/01/2017 01:33 PM	Final Report

AMENDED REPORT - please replace all previous reports

CBC (INCLUDES DIFF/PLT)

Test	Within Range	Out of Range		Biological Ref Range	Units
HEMOGLOBIN		**12.2**	**L**	13.2 - 17.1	g/dL
HEMATOCRIT		**37.6**	**L**	38.5 - 50.0	%
WHITE BLOOD CELL COUNT	5.2			3.8 - 10.8	Thousand/uL
NEUTROPHILS	54.9			40.0 - 75.0	%
LYMPHOCYTES	32.6			16.0 - 46.0	%
MONOCYTES	7.7			0.0 - 12.0	%
EOSINOPHILS	4.5			0.0 - 7.0	%
BASOPHILS	0.3			0.0 - 2.0	%
NUCLEATED RBC	0.0				/100 WBC
PLATELET COUNT	226			140 - 400	Thousand/uL
ABSOLUTE NEUTROPHILS	2855			1500 - 7800	cells/uL
ABSOLUTE LYMPHOCYTES	1695			850 - 3900	cells/uL
ABSOLUTE MONOCYTES	400			200 - 950	cells/uL
ABSOLUTE EOSINOPHILS	234			15 - 550	cells/uL
ABSOLUTE BASOPHILS	16			0 - 200	cells/uL
RED BLOOD CELL COUNT	4.21			4.20 - 5.80	Million/uL
MCV	89.3			80.0 - 100.0	fL
MCH	28.9			27.0 - 33.0	pg
MCHC	32.3			32.0 - 36.0	g/dL
RDW	14.0			11.0 - 15.0	%
MPV		**13.3**	**H**	7.5 - 11.5	fL
MENTZER INDEX	21.21				

METHOD - CALCULATED

The Mentzer index is used to differentiate iron deficiency anemia from beta thalassemia trait. If a CBC indicates microcytic anemia, these are two of the most likely causes, making it necessary to distinguish between them.

If the quotient of the mean corpuscular volume divided by the red blood cell count is less than 13, thalassemia is more likely. If the result is greater than 13, then iron-deficiency anemia is more likely.

Panel Comments
CBC (INCLUDES DIFF/PLT)
METHOD : CELL COUNTER

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Thank You

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