TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

UIBC REAGENT
TC MATRIX-240/480

INTENDED USE
The test is applied for quantitative determination of unsaturated iron-binding capacity (UIBC) in human serum.

SUMMARY AND PRINCIPLE[1, 2, 3, 4, 5]
Transferrin is the carrier protein in the blood and is normally 20% to 50% saturated at the two iron binding sites. The amount of additional iron that can be bound is the unsaturated iron binding capacity (UIBC). The sum of serum iron and UIBC represents the total iron binding capacity (TIBC).

The serum UIBC level varies according to the disorder of iron metabolism, iron binding capacity is generally increased in iron disorders and decreased in chronic inflammatory disorders or malignant ones.

In the detection of various iron disorders, measurement of UIBC in combination with serum iron is a useful diagnostic tool.

UIBC measurements are used in the diagnosis and treatment of anemia.

Direct determination of FerroZine 4,5

$$Fe(II) + Transferrin \xrightarrow{Alkaline\ Buffer} Transferrin - Fe(III) + Fe(II)(excess)$$

$$Fe(II)(excess) + 3\ FerroZine\ Fe(II) \rightarrow (FerroZine)3$$

The color intensity is directly proportional to the excess unbound iron concentration and indirectly proportional to the unsaturated iron binding capacity.

REAGENTS
Each kit contains:

Reagent 1:

Buffer	≥0.2 mol/L, pH 8.45
Ferrous ammonium sulphate	≥8.4 p umol/L
Hydroxylamine hydrochloride	≥0.1mol/L
Nonionic surfactant	

Reagent 2:

Ferrozine	⩽24.3 mmol/L
Preservative	<0.1%

REAGENT PREPARATION
Reagents are ready for use.

PRECAUTIONS
IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

REAGENT STORAGE AND STABILITY[6]
Reagents are stable at 2-8°C until the expiration date stated on the label which is only for closed vials.

Once opened vials are stable for 30 days at 2-8°C in optimum conditions. On board stability is strongly related to auto analyzers' cooling specification and carry-over values.

Reagent stability and storage have been verified by using Clinical and Laboratory Standards Institute (CLSI) EP25-A protocol.

SPECIMEN STORAGE[7, 8]
Serum and plasma are collected according to the standard procedure.
Serum and plasma are stable for:
4 days at 20-25°C,
7 days at 2-8°C,
1 year at -70°C.

Use serum or heparinized plasma. Do not use samples with EDTA, Oxalate, Citrate. Do not use hemolyzed samples. To avoid hemolysis; centrifuge and separate samples immediately, after collecting samples.

INTERFERING SUBSTANCES[14, 15, 16]
No significant interactions were observed for hemoglobin, conjugated bilirubin, lipemia up to the interferent concentration given in the table.

Interfering Substance and Concentration	Lipase Target (mg/dL)	N	Observed Recovery %
Hemoglobin 270 mg/dL	212	3	108
Bilirubin 6.93 mg/dL	245	3	91
Lipemia 4470 mg/dL	219	3	102

The acceptable interference limit is set 10% below the highest interference concentration within + 10% recovery of the target.

Interferences may affect the results due to medication or endogenous substances.

These performance characteristics have been obtained by using an analyzer. Results may vary if a different instrument or a manual procedure is used.

PROCEDURE

Test Name:	UIBC	R1:	150
Full Name:	UIBC	R2:	36
Pri. Wave:	578 nm	SAMPLE VOLUME:	13
Sec. Wave:	700 nm	Calibration Type:	2 Point Linear
Assay/ Point:	2-point End	K Value:	/
Start - End:	13 - 33	Point:	2
Decimal place:	1	Blank Type:	Reagent
Unit:	ug/dL	Point 0 (Blank) Con.:	0.0
Linearity Range:	10 - 600	Point 1 (CAL) Con.:	Calibrator/ standard
Correlation Factor:	1.0000 - 0.0000		

QUALITY CONTROL AND CALIBRATION
Commercially available control material with established values determined by this method may be used.

The assay requires the use of an UIBC Standard (Calibrator) /Auto Calibrator.
UIBC kit must be calibrated.
For the UIBC Calibrator, the calibrator value must be entered as a negative number.
Calibration Stability: It strongly depends on the application characteristics of in-use auto analyzer and capacity of cooling. Calibration stability is 5 days.

If controls are not within acceptable limits, calibration is required and each laboratory should establish its own Quality Control diagrams and corrective and preventive action procedures.

Quality control is recommended every morning. Calibration is not recommended if quality control values are acceptable. Reagent should be calibrated after lot changes.

EXPECTED VALUES
Normal Range:

UIBC	120-370 ug/dL
TIBC	127-450 ug/dL

It is recommended that each laboratory establish its own normal range.
Reference interval has been verified by using CLSI EP28-A3c protocol.

PERFORMANCE CHARACTERISTICS
Limit of Detection (LoD): The limit of detection is 10 ug/dL.

Limit of Quantitation (LoQ) [LoQ values are based on Coefficient of Variation Percentage (CV) ⩽20%]:[10] 20 ug/dL

LoD and LoQ values have been verified by using CLSI EP17-A protocol.

Precision[11]**:**

	Repeatability		
Mean Concentration (ug/dL)	**SD**	**CV%**	**n**
126.65	4.31	3.4	40
243.25	4.89	2.01	40

	Reproducibility		
Mean Concentration (ug/dL)	**SD**	**CV%**	**n**
150.29	8.49	5.65	84
217.96	10.74	4.92	84

±10% CV% differences can be observed between devices.
Precision Studies data have been verified by using CLSI EP05-A3 protocol.

Linearity: The method is linear up to 600 ug/dL.
For values above high linearity, dilute sample with 0.9% saline, repeat the test and multiply the result by the dilution factor.
Linearity may considerably vary depending on the instrument used.

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Manufactured by:

TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
U.S.A.
Website: www.tecodiagnostics.com