

Master File Identification

Element name	Data
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[1]

Master File Entry

Element name	Data
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General Segment

Element name	Data
Observations Required to Interpret the Observation	Fasting status [Presence] - reported
Observations Required to Interpret the Observation	Race
Interpretation of Observations	Test used to measure blood sugar, electrolytes and fluid balance, kidney and liver function.
Patient Preparation	Patient fasting required for 12 hours.
Service/Test/Observation Performance Schedule	Daily
Other Names	CMP
Expected Turn-Around Time	1 day

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	Serum Glucose
Test/Observations Included Within an Ordered Test Battery [2]	Blood Urea Nitrogen (BUN)
Test/Observations Included Within an Ordered Test Battery [3]	Creatinine
Test/Observations Included Within an Ordered Test Battery [4]	BUN/Creatinine Ratio
Test/Observations Included Within an Ordered Test Battery [5]	GFR, calculated
Test/Observations Included Within an Ordered Test Battery [6]	Calcium
Test/Observations Included Within an Ordered Test Battery [7]	Total protein, serum
Test/Observations Included Within an Ordered Test Battery [8]	Albumin
Test/Observations Included Within an Ordered Test Battery [9]	Globulin
Test/Observations Included Within an Ordered Test Battery [10]	Albumin/globulin ratio
Test/Observations Included Within an Ordered Test Battery [11]	Total bilirubin, serum
Test/Observations Included Within an Ordered Test Battery [12]	Alkaline phosphatase (ALP)
Test/Observations Included Within an Ordered Test Battery [13]	Alanine aminotransferase (ALT)
Test/Observations Included Within an Ordered Test Battery [14]	Aspartate aminotransferase (ASP)
Test/Observations Included Within an Ordered Test Battery [15]	Sodium, serum

Test/Observations Included Within an Ordered Test Battery [16]	Potassium, serum
Test/Observations Included Within an Ordered Test Battery [17]	Chloride, serum
Test/Observations Included Within an Ordered Test Battery [18]	Carbon dioxide, serum
Test/Observations Included Within an Ordered Test Battery [19]	Anion gap

Observations that Require Specimens

Element name	Data
Container Description	Gold Serum Separator tube
Container Description	Red, No Additive tube
Container Volume	5.0
Container Volume	5.0
Container Units	mililiter
Container Units	mililiter
Specimen Handling Code	Refrigerated temperature

[2]

Master File Entry

Element name	Data
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General Segment

Element name	Data
Interpretation of Observations	Urinalysis is used to detect and assess a wide range of disorders. This panel includes a opacity, color, appearance, specific gravity, pH, protein, glucose, occult blood, ketones, bilirubin, nitrite, and microscopic examination of the urine sediment.
Patient Preparation	Collect random urine in a clean plastic container. Label the urine container with the patient's full name and the date and time of collection, refrigerate after collection.
Patient Preparation	Both males and females need instructions on cleaning the urethral opening. A "midstream catch" is performed by initially urinating into the toilet then bringing the collection device into the urine stream to obtain the midportion of the void. For infants and young children urine can be collected by urine bag, catheterization or cystocentesis. A clean catch sample is preferred, when contamination from vaginal hemorrhage or discharge is suspected. If the specimen is obtained by catheterization, the collection method must be noted.
Service/Test/Observation Performance Schedule	Daily
Expected Turn-Around Time	1 day

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	Color of Urine
Test/Observations Included Within an Ordered Test Battery	

[2]	Clarity of Urine
Test/Observations Included Within an Ordered Test Battery [3]	Erythrocytes, urine
Test/Observations Included Within an Ordered Test Battery [4]	Leukocytes, urine
Test/Observations Included Within an Ordered Test Battery [5]	Leukocyte clumps, urine
Test/Observations Included Within an Ordered Test Battery [6]	Non-squamous epithelial cells. , urine
Test/Observations Included Within an Ordered Test Battery [7]	Squamous epithelial cells. , urine
Test/Observations Included Within an Ordered Test Battery [8]	Bacteria, urine
Test/Observations Included Within an Ordered Test Battery [9]	Crystals , urine
Test/Observations Included Within an Ordered Test Battery [10]	Hyaline casts
Test/Observations Included Within an Ordered Test Battery [11]	Casts
Test/Observations Included Within an Ordered Test Battery [12]	Spermatozoa, urine
Test/Observations Included Within an Ordered Test Battery [13]	Mucus,urine
Test/Observations Included Within an Ordered Test Battery [14]	Total bilirubin,urine
Test/Observations Included Within an Ordered Test Battery [15]	Glucose, urine
Test/Observations Included Within an Ordered Test Battery [16]	Hemoglobin, urine
Test/Observations Included Within an Ordered Test Battery [17]	Ketones , urine
Test/Observations Included Within an Ordered Test Battery [18]	Leukocyte esterase, urine
Test/Observations Included Within an Ordered Test Battery [19]	Nitrite, urine
Test/Observations Included Within an Ordered Test Battery [20]	Urine pH
Test/Observations Included Within an Ordered Test Battery [21]	Protein, urine
Test/Observations Included Within an Ordered Test Battery [22]	Urobilinogen
Test/Observations Included Within an Ordered Test Battery [23]	Urine specific gravity

Observations that Require Specimens

Element name	Data
Container Description	Sterile, plastic, leak proof container
Container Volume	4
Container Units	fluid ounce (US)
Specimen Handling Code	Refrigerated temperature

Master File Entry

Element name	Data
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General Segment

Element name	Data
Interpretation of Observations	A CBC is used to evaluate red blood cells , white blood cells , and platelet and helps detect and assess a wide range of disorders. This panel includes a WBC count, differential count, Hct, Hb, RBC count, WBC and RBC Morphology, RBC indices, platelet estimate, platelet count, RDW, and histogram.
Service/Test/Observation Performance Schedule	Daily
Prior Results Instructions	Send prior results for CBC in past 60 days
Expected Turn-Around Time	1 day

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	Erythrocytes, blood
Test/Observations Included Within an Ordered Test Battery [2]	Hemoglobin (Hb)
Test/Observations Included Within an Ordered Test Battery [3]	Hematocrit
Test/Observations Included Within an Ordered Test Battery [4]	Leukocytes, blood
Test/Observations Included Within an Ordered Test Battery [5]	Platelets
Test/Observations Included Within an Ordered Test Battery [6]	Mean corpuscular volume (MCV)
Test/Observations Included Within an Ordered Test Battery [7]	Mean corpuscular hemoglobin (MCH)
Test/Observations Included Within an Ordered Test Battery [8]	Mean corpuscular hemoglobin Concentration (MCHC)
Test/Observations Included Within an Ordered Test Battery [9]	Red blood cell distribution width (RDW)
Test/Observations Included Within an Ordered Test Battery [10]	Basophils
Test/Observations Included Within an Ordered Test Battery [11]	% Basophils
Test/Observations Included Within an Ordered Test Battery [12]	Monocytes
Test/Observations Included Within an Ordered Test Battery [13]	% Monocytes
Test/Observations Included Within an Ordered Test Battery [14]	Eosinophils
Test/Observations Included Within an Ordered Test Battery [15]	% Eosinophils
Test/Observations Included Within an Ordered Test Battery [16]	Lymphocytes
Test/Observations Included Within an Ordered Test Battery [17]	% Lymphocytes

Test/Observations Included Within an Ordered Test Battery [18]	Neutrophils
Test/Observations Included Within an Ordered Test Battery [19]	% Neutrophils
Test/Observations Included Within an Ordered Test Battery [20]	Anisocytosis
Test/Observations Included Within an Ordered Test Battery [21]	Hypochromia
Test/Observations Included Within an Ordered Test Battery [22]	Macrocytosis
Test/Observations Included Within an Ordered Test Battery [23]	Microcytosis
Test/Observations Included Within an Ordered Test Battery [24]	Poikilocytosis
Test/Observations Included Within an Ordered Test Battery [25]	Polychromasia
Test/Observations Included Within an Ordered Test Battery [26]	RBC morphology
Test/Observations Included Within an Ordered Test Battery [27]	WBC morphology
Test/Observations Included Within an Ordered Test Battery [28]	Platelet morphology

Observations that Require Specimens

Element name	Data
Container Description	Lavender Top (EDTA) tube
Container Description	Pink Top (K2EDTA) tube
Container Volume	3.0
Container Volume	3.0
Container Units	milliliters
Container Units	milliliters
Specimen Handling Code	Critical refrigerated

[4]

Master File Entry

Element name	Data
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General Segment

Element name	Data
Observations Required to Interpret the Observation	Fasting status [Presence] - reported
Observations Required to Interpret the Observation	Race
Interpretation of Observations	This blood test is used to determine general health status and to screen for and monitor a variety of disorders. This profile includes a complete metabolic profile, comprehensive CBC, Urinalysis and total Thyrotropin (T4).
Patient Preparation	Patient fasting required for 12 hours.
Service/Test/Observation Performance Schedule	Daily
Expected Turn-Around Time	1 day

Observation batteries

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Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	CMP
Test/Observations Included Within an Ordered Test Battery [2]	CBC_diff
Test/Observations Included Within an Ordered Test Battery [3]	TSH
Test/Observations Included Within an Ordered Test Battery [4]	Comprehensive Urinalysis

Observations that Require Specimens

Element name	Data
Container Description	Gold Serum Separator tube
Container Description	Red, No Additive tube
Container Volume	5.0
Container Volume	5.0
Container Units	mililiter
Container Units	mililiter
Specimen Handling Code	Refrigerated temperature

Observations that Require Specimens

Element name	Data
Container Description	Lavender Top (EDTA) tube
Container Description	Pink Top (K2EDTA) tube
Container Volume	3.0
Container Volume	3.0
Container Units	milliliters
Container Units	milliliters
Specimen Handling Code	Critical refrigerated

Observations that Require Specimens

Element name	Data
Container Description	Sterile, plastic, leak proof container
Container Volume	4
Container Units	fluid ounce (US)
Specimen Handling Code	Refrigerated temperature

[5]

Master File Entry

Element name	Data
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General Segment

Element name	Data
Reflex Tests/Observations	Hepatitis C RNA PCR
Rules that Trigger Reflex Testing	Negative: < 0.8; Indeterminate 0.8 - 0.9; Positive: > 0.9. In order to reduce the incidence of a false positive result, the CDC recommends that all s/co ratios between 1.0 and 10.9 be confirmed with additional Verification or PCR testing.

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	Hepatitis A IgM antibodies (IgM anti-HAV)
Test/Observations Included Within an Ordered Test Battery [2]	Hepatitis A antibodies (anti-HAV)
Test/Observations Included Within an Ordered Test Battery [3]	Hepatitis B core antibodies (anti-HBVC)
Test/Observations Included Within an Ordered Test Battery [4]	Hepatitis B core antibodies (anti-HBVC) Quant
Test/Observations Included Within an Ordered Test Battery [5]	Hepatitis B e antibodies (anti-HBVe)
Test/Observations Included Within an Ordered Test Battery [6]	Hepatitis B surface antigen (HBsAg)
Test/Observations Included Within an Ordered Test Battery [7]	Hepatitis B surface antibody (anti-HBs)
Test/Observations Included Within an Ordered Test Battery [8]	Hepatitis C antibody screen (anti-HCV)
Test/Observations Included Within an Ordered Test Battery [9]	Hepatitis C antibodies Signal to Cut-off Ratio
Test/Observations Included Within an Ordered Test Battery [10]	Hepatitis C RNA PCR

Observations that Require Specimens

Element name	Data
Container Description	Gold Serum Separator tube
Container Volume	5.0
Container Units	milliliter
Specimen Handling Code	Frozen

[6]

Master File Entry

Element name	Data
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General Segment

Element name	Data
Service/Test/Observation Performance Schedule	Monday through Friday
Expected Turn-Around Time	2 day

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	Dengue Virus IgG Titer Serum
Test/Observations Included Within an Ordered Test Battery [2]	Dengue Virus IgM Titer Serum
Test/Observations Included Within an Ordered Test Battery [3]	WNV IgG Titer Serum
Test/Observations Included Within an Ordered Test Battery [4]	WNV Virus IgM Titer Serum

Observations that Require Specimens

Element name	Data
Container Description	Gold Serum Separator tube
Container Description	Red, No Additive tube
Container Volume	5.0
Container Volume	5.0
Container Units	mililiter
Container Units	mililiter
Specimen Handling Code	Refrigerated temperature

[7]

Master File Entry

Element name	Data
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General Segment

Element name	Data
Observations Required to Interpret the Observation	Race
Service/Test/Observation Performance Schedule	Monday through Friday
Expected Turn-Around Time	1 day

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	Urine Volume of 24 hour collection
Test/Observations Included Within an Ordered Test Battery [2]	Creatinine Clearance in 24 hours
Test/Observations Included Within an Ordered Test Battery [3]	Creatinine
Test/Observations Included Within an Ordered Test Battery [4]	GFR, calculated
Test/Observations Included Within an Ordered Test Battery [5]	Creatinine in 24 hr Urine
Test/Observations Included Within an Ordered Test Battery [6]	What is the Clinically Relevant Race?

Observations that Require Specimens

Element name	Data
Container Description	Sterile, plastic, leak proof container
Container Volume	2000
Container Units	milliliter
Specimen Handling Code	Refrigerated temperature

Observations that Require Specimens

Element name	Data
Container Description	Lavender Top (EDTA) tube
Container Description	Pink Top (K2EDTA) tube
Container Volume	3.0
Container Volume	3.0

Container Units	milliliters
Container Units	milliliters
Specimen Handling Code	Critical refrigerated