Master File Identification

Element name	Data
THILE-LEVEL EVENT LOGE	Replace current version of this master file with the version
	contained in this message

Battery information [1]

Master File Entry

Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	CMP

General Segment

Element name	Data
Specimen Required	Yes
Producer ID	Century Hospital Clinical Laboratory
Other Service/Test/Observation IDs for the Observation	Comprehensive metabolic 2000 panel - Serum or Plasma
Preferred Short Name or Mnemonic for Observation	CMP
Orderability	Yes
Nature of Service/Test/Observation	P
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.
Factors that may Affect the Observation	Insufficient specimen, Gross hemolysis, Improper labeling
Service/Test/Observation Performance Schedule	Daily
Exclusive Test	This test can be included with any number of other tests
Diagnostic Service Sector ID	Laboratory
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

Element name	Data
Sequence Number - Test/Observation Master File	1
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	Serum specimen
Normal Collection Volume	1 milliliter
Minimum Collection Volume	0.5 milliliter
Specimen Requirements	Protect from light. Allow serum tube to clot completely at room temperature. Separate serum or plasma from cells ASAP or within 30 minutes of collection.
Specimen Handling Code	Refrigerated temperature
Specimen Preference	Preferred

Battery information [2]

Master File Entry

Widstell inc Entry	
Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	Comprehensive Urinalysis

General Segment

Element name	Data
Specimen Required	Yes
Producer ID	Century Hospital Clinical Laboratory
Other Service/Test/Observation IDs for the Observation	Urinalysis panel - Urine by Auto
Preferred Report Name for the Observation	Comprehensive Urinalysis
Orderability	Yes
Nature of Service/Test/Observation	P
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 catherization, the collection method must be noted.
Factors that may Affect the Observation	Insufficient specimen, improper labeling, presence of preservatives, fecal contamination, bacterial overgrowth. Delay in transport.
Service/Test/Observation Performance Schedule	Daily
Exclusive Test	This test can be included with any number of other tests
Diagnostic Service Sector ID	Laboratory
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

Element name	Data
Sequence Number - Test/Observation Master File	2
Container Description	Sterile, plastic, leak proof container
Container Volume	4
Container Units	fluid ounce (US)
Specimen	Urine specimen
Normal Collection Volume	20 milliliter
Minimum Collection Volume	4 milliliter
Specimen Requirements	Keep refrigerated
Specimen Handling Code	Refrigerated temperature
Specimen Preference	Preferred

Battery information [3]

Master File Entry

Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	CBC_diff

General Segment

Element name	Data
Specimen Required	Yes
Producer ID	Century Hospital Clinical Laboratory
Other Service/Test/Observation IDs for the Observation	CBC W Auto Differential panel in Blood
Preferred Report Name for the Observation	Complete Blood Count
Orderability	Yes
Nature of Service/Test/Observation	P
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.
Factors that may Affect the Observation	Insufficient specimen, Improper labeling, improper tube, clotted specimen, hemolyzed sample, dilution of blood.
Service/Test/Observation Performance Schedule	Daily
Exclusive Test	This test can be included with any number of other tests
Diagnostic Service Sector ID	Laboratory
Prior Resuts 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

Element name	Data
Sequence Number - Test/Observation Master File	3
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	Blood sample
Additive	Potassium/K EDTA
Normal Collection Volume	3 milliliters
Minimum Collection Volume	0.5 milliliters
Specimen Requirements	Refrigeration is required if specimen is not brought immediately to laboratory. Two blood smears should be prepared if sample is not delivered to the laboratory within 4 hrs. Sample should be analyzed within 6 hours at room temperature and 24 hrs when stored at 4 degrees C.
Specimen Handling Code	Critical refrigerated
Specimen Preference	Preferred

Battery information [4]

Master File Entry

=======================================	
Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	GHP Profile

General Segment

Element name	Data
Specimen Required	Yes
Producer ID	Century Hospital Clinical Laboratory
Preferred Report Name for the Observation	General Health Profile
Orderability	Yes
Nature of Service/Test/Observation	S
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.
Factors that may Affect the Observation	Insufficient specimen, Gross hemolysis, Improper labeling
Service/Test/Observation Performance Schedule	Daily
Exclusive Test	This test can be included with any number of other tests
Diagnostic Service Sector ID	Laboratory
Expected Turn-Around Time	1 day

Observation batteries

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

Element name	Data
Sequence Number - Test/Observation Master File	4.1
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	Serum specimen

Normal Collection Volume	1 milliliter
Minimum Collection Volume	0.5 milliliter
Specimen Requirements	Protect from light. Allow serum tube to clot completely at room temperature. Separate serum or plasma from cells ASAP or within 30 minutes of collection.
Specimen Handling Code	Refrigerated temperature
Specimen Preference	Preferred

Element name	Data
Sequence Number - Test/Observation Master File	4.2
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	Blood sample
Additive	Potassium/K EDTA
Normal Collection Volume	3 milliliters
Minimum Collection Volume	0.5 milliliters
Specimen Requirements	Refrigeration is required if specimen is not brought immediately to laboratory. Two blood smears should be prepared if sample is not delivered to the laboratory within 4 hrs. Sample should be analyzed within 6 hours at room temperature and 24 hrs when stored at 4 degrees C.
Specimen Handling Code	Critical refrigerated
Specimen Preference	Preferred

Observations that Require Specimens

Element name	Data
Sequence Number - Test/Observation Master File	4.3
Container Description	Sterile, plastic, leak proof container
Container Volume	4
Container Units	fluid ounce (US)
Specimen	Urine specimen
Normal Collection Volume	20 milliliter
Minimum Collection Volume	4 milliliter
Specimen Requirements	Keep refrigerated
Specimen Handling Code	Refrigerated temperature
Specimen Preference	Preferred

Battery information [5]

Master File Entry

Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	Hepatitis A B C Panel_With Reflex

General Segment

Element name	Data
Specimen Required	Yes
Producer ID	Century Hospital Clinical Laboratory
Preferred Report Name for the Observation	Hepatitis A B C Panel_With Reflex
Orderability	Yes
Nature of Service/Test/Observation	P
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.
Factors that may Affect the Observation	Performance characteristics have not been established for the following types of specimen: -Grossly icteric (total bilirubin level of >15 mg/dL) -Grossly lipemic (triolein level of >3,000 mg/dL) -Grossly hemolyzed (hemoglobin level of >500 mg/dL) -Presence of particulate matter -Cadaveric specimen

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-HBVs)
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

Element name	Data
Sequence Number - Test/Observation Master File	5
Container Description	Gold Serum Separator tube
Container Volume	5.0
Container Units	mililiter
Specimen	Serum specimen
Normal Collection Volume	4 mililiter
Minimum Collection Volume	2.5 mililiter

Specimen Requirements	Spin down and remove serum from clot within 6 hours.
Specimen Handling Code	Frozen
Specimen Preference	Preferred

Battery information [6]

Master File Entry

Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	Arbovirus IgG and IgM Panel (DNG, WNV) in Serum

General Segment

Element name	Data
Specimen Required	No
Producer ID	Century Hospital Clinical Laboratory
Preferred Report Name for the Observation	Arbovirus Panel for Dengue, West Nile Virus
Orderability	Yes
Nature of Service/Test/Observation	P
Factors that may Affect the Observation	Insufficient specimen, Improper labeling
Service/Test/Observation Performance Schedule	Monday through Friday
Exclusive Test	This test can be included with any number of other tests
Diagnostic Service Sector ID	Laboratory
Expected Turn-Around Time	2 day

Observation batteries

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

Element name	Data
Sequence Number - Test/Observation Master File	6
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	Serum specimen
Normal Collection Volume	1 milliliter
Minimum Collection Volume	0.5 milliliter
	Protect from light. Allow serum tube to clot completely at

	room temperature. Separate serum or plasma from cells ASAP or within 30 minutes of collection.
Specimen Handling Code	Refrigerated temperature
Specimen Preference	Preferred

Battery information [7]

Master File Entry

Element name	Data
Record-Level Event Code	Add record to master file
Effective Date/Time	2013-12-19 2:53:10pm
Primary Key Value - MFE	Creatinine Clearance

General Segment

Element name	Data
Specimen Required	Yes
Producer ID	Century Hospital Clinical Laboratory
Other Service/Test/Observation IDs for the Observation	Creatinine 24H renal clearance panel
Preferred Report Name for the Observation	Creatinine Clearance
Orderability	Yes
Nature of Service/Test/Observation	P
Observations Required to Interpret the Observation	Race
Factors that may Affect the Observation	Insufficient specimen, Improper labeling
Service/Test/Observation Performance Schedule	Monday through Friday
Exclusive Test	This test can be included with any number of other tests
Diagnostic Service Sector ID	Laboratory
Expected Turn-Around Time	1 day

Observation batteries

Element name	Data
Test/Observations Included Within an Ordered Test Battery [1]	
Test/Observations Included Within an Ordered Test Battery [2]	
Test/Observations Included Within an Ordered Test Battery [3]	
Test/Observations Included Within an Ordered Test Battery [4]	
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?

Element name	Data
Sequence Number - Test/Observation Master File	7.1
Container Description	Sterile, plastic, leak proof container
Container Volume	2000
Container Units	milliliter

Specimen	Urine specimen
Normal Collection Volume	20 milliliter
Minimum Collection Volume	4 milliliter
Specimen Requirements	Keep refrigerated
Specimen Handling Code	Refrigerated temperature
Specimen Preference	Preferred

Element name	Data
Sequence Number - Test/Observation Master File	7.2
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	Blood sample
Additive	Potassium/K EDTA
Normal Collection Volume	3 milliliters
Minimum Collection Volume	0.5 milliliters
Specimen Requirements	Refrigeration is required if specimen is not brought immediately to laboratory. Two blood smears should be prepared if sample is not delivered to the laboratory within 4 hrs. Sample should be analyzed within 6 hours at room temperature and 24 hrs when stored at 4 degrees C.
Specimen Handling Code	Critical refrigerated
Specimen Preference	Preferred