

# Updated Diagnostic Cortisol Values for Adrenal Insufficiency

NCT05149638

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Montefiore Medical Center
Enrollment	90 participants

## Key Eligibility Criteria

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### Inclusion (3)

- Male and female outpatients 18 years or older without prior diagnosis of primary or central adrenal insufficiency
- Males and females 18 years or older with established diagnosis of primary or central adrenal insufficiency as previously documented in the electronic medical record by a failed CST (peak cortisol level  $< 18 \mu\text{g/dL}$ ) or morning serum cortisol  $< 3 \text{ mcg/dL}$  with an appropriate clinical circumstance (e.g., Sheehan's syndrome, pituitary surgery and/or irradiation, bilateral adrenalectomy, etc.) that strongly supports a true diagnosis of primary or central adrenal insufficiency, and current use of physiologic, replacement dose glucocorticoids. Inpatients with non-critical illness and outpatients are eligible
- Males and females 18 years or older with suspected diagnosis of primary or central adrenal insufficiency by any cause based on clinical evaluation by a study team member. Inpatients with non-critical illness and outpatients are eligible

### Exclusion (20)

- Moderate to severe liver impairment or abnormal albumin or cortisol binding globulin concentrations
  - Renal impairment with estimated Glomerular Filtration Rate (eGFR)  $< 60 \text{ mL/min/1.73m}^2$  and/or diagnosis of nephrotic syndrome
  - Pregnancy or nursing mothers
  - Use of estrogen preparations
  - Uncontrolled major depressive disorder or psychiatric diseases, severe malnutrition, eating disorders, chronic fatigue syndrome (disorders that alter hypothalamic-pituitary-adrenal (HPA) axis function)
- ... and 15 more (see full listing online)

## Locations (1 total)

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Montefiore Medical Center, The Bronx, New York, United States