Exhibit E
Peripheral Neuropathy Research Registry (PNRR)
Standard Operating Procedure (SOP) for Peripheral Nerve Workup Form (PNW)

PERIPHERAL NERVE WORKUP FORM (PNW)

The Peripheral Nerve Workup Form (PNW) has to be filled out at the time a new patient is enrolled into the PNRR study. Only testing conducted within 36 months before or after enrollment visit should be reported in the PNW form, with the exception of genetic and HIV testing.

The FIRST TIER testing is considered the Minimum Data Set (MDS) and must be provided for all PNRR subjects.

The SECOND TIER testing is considered high desired, and all available testing results should be entered into REDCap.

GENERAL INFORMATION (all fields required):

- **Physician**: last name of the physician performing the study visit
- **Sex:** genetic sex of the PNRR participant
- **Year of visit:** year of the visit this PNW form is associated with
- **Year of birth:** year the PNRR participant was born

FIRST TIER

All tests listed in the first tier are part of the minimum data set and are required for new PNRR enrollments. However, for newly-enrolled patients with small fiber neuropathy, the requirement for Nerve Conduction Study / Electromyography can be waived if the diagnosis is supported by PEF and PHQ information or skin biopsy results are provided.

NOTE: If a patient had NCS testing outside of the 36 months window, the NCS interpretation should still be entered into the PNW form, together with the year of testing, but the NCS form itself should not be completed.

1. Nerve Conduction Study / Electromyography (NCS/EMG) diagnosis

The physician interpretation from the NCS/EMG testing should be reported

Data Entry:
Normal: nerve function is within the normal range.
Abnormal: test detected significant nerve dysfunction of one or more nerves
ND/NA: no NCS/EMG testing was conducted with this patient
Year of Test: calendar year when the test was done. Must be within 36 months to visit.

If abnormal (mark one):
Sensory: predominantly sensory nerves are affected by neuropathy
Motor: predominantly motor nerves are affected by neuropathy
Sensorimotor: both motor and sensory nerves are affected by neuropathy

AND (mark one):

Axonal: the primary process is consistent with axon loss neuropathy
Demyelinating: the primary process is consistent with demyelinating neuropathy
Mixed: both axonal damage and demyelinating neuropathy

2. Skin biopsy (if NCS/EMG is normal):

For patients who have a normal NCS/EMG result, skin biopsy testing results should be provided.

Data Entry:
Normal: skin biopsy results were normal
Abnormal: skin biopsy results were abnormal, confirming small fibers are affected
ND/NA: no skin biopsy was performed
Year of Test: calendar year skin biopsy was performed, should be within 36 months of visit

If abnormal (mark one):
Length-Dependent: nerve fiber density is more reduced at the distal site
Not Length-Dependent: nerve fiber densities are reduced at both proximal and distal sites

3. Chemistry 12-18

Creatinine level from the most recent Comprehensive Metabolic Panel (CMP) should be reported in milligram per deciliter (mg/dL). Creatinine levels ≥ 1.4 mg/dL should be reported as abnormal. Creatinine levels reported in nmol/L should be converted into mg/dL.

Data Entry:
Normal: creatinine value is within normal range (≤ 1.3 mg/dL)
Abnormal: creatinine value is outside the normal range (≥ 1.4 mg/dL)
ND/NA: no Chemistry panel was done in the past 36 months, or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Creatinine level: enter measured creatinine value inmg/dL

4. Glucose

The test results of at least one of the three tests approved as glucose screening tests has to be performed with each PNRR participant to exclude or confirm the diagnosis of diabetes mellitus (DM) or prediabetes as the cause of neuropathy.

a. Glycated Hemoglobin (HbA1C)

The glycated hemoglobin value is an indicator for hyperglycemia. If HbA1C value was analyzed within the past 36 months, it should be reported here in % glycated hemoglobin. For PNRR, HbA1c of 5.7% or higher is considered abnormal.

Data Entry:
Normal: measured HbA1c % was within the reference range (≤ 5.6%)
Abnormal: measured HbA1c % was higher than the reference range (≥ 5.7%)

ND/NA: test was not performed within last 36 months, or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
HbA1C Level: enter measured HbA1c level in % of total hemoglobin

b. Blood Glucose (fasting)

Expresses the amount of glucose in blood after a minimum of 8 hour fasting, abnormal testing results should only be provided if study personnel can verify that blood was collected while patient was fasting. For PNRR, fasting blood glucose levels ≥ 100 mg/dL are considered abnormal. Fasting glucose levels reported in mmol/L shall be converted to mg/dL.

Data Entry:

Normal: fasting glucose within normal range (≤ 99 mg/dL)
Abnormal: fasting glucose outside the normal range (≥ 100 mg/dL)
ND/NA: test was not performed within the last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Fasting Glucose level: enter measured fasting glucose level in mg/dL

c. Oral Glucose Tolerance test

Blood glucose levels measured 2 hours after patient drank glucose syrup should be reported in milligram per deciliter (mg/dL). Both abnormal high (hyperglycemic, ≥140 mg/dL) and abnormal low (hypoglycemic, ≤ 70 mg/dL) test results should be reported as abnormal. Testing results reported in mmol/L should be converted to mg/dL.

Data Entry:

Normal: test result within normal range (70-139 mg/dL)
Abnormal: blood glucose levels after 2 hours were abnormal low (≤ 70 mg/dL) or abnormal high (≥140 mg/dL).
ND/NA: test was not performed within the last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Glucose level: measured 2-hour glucose in mg/dL)

5.a. Serum Immunofixation (SIFE) and/or

5.b Serum Protein Electrophoresis (SPEP)

Both tests evaluate Immunoglobulin (antibodies) and protein levels in serum. If Serum Immunofixation (SIFE) results are reported abnormal, Serum Protein Electrophoresis (SPEP) is required.

Data Entry:

Normal: all screened immunoglobulins are within normal range
Abnormal: one or more immunoglobulins are outside of normal range
ND/NA: test was not performed within the last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

If SIFE and/or SPEP were abnormal:
Identification of type of abnormality:

- Monoclonal gammopathy – presence of paraprotein (abnormal high levels)
- Hypoglobulinemia – one or more values are in abnormal low range

And the protein(s) for which abnormal level(s) were detected should be identified

- Immunoglobulin A (IgA)
- Immunoglobulin G (IgG)
- Immunoglobulin M (IgM)
- Kappa Light Chain
- Lambda Light Chain
- Other

6. Vitamin B12

Measured Vitamin B12 (or cobalamin) levels in blood reported in picogram per milliliter (pg/mL). Reported values below the normal range (180 pg/mL) should be reported as abnormal in PNRR. High values are of little concern and are common in patients who take Vitamin B supplements and should not be reported as abnormal. Vitamin B12 levels measured in pmol/L should be converted to pg/mL before entered into the database.

Data Entry:

Normal: Vitamin B12 values in normal range or elevated
Abnormal: Vitamin B12 value is below normal range < 180 pg/mL
ND/NA: test was not performed within the last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Vitamin B12 Value: enter measured Vitamin B12 value in pg/mL

SECOND TIER

The Second Tier lists standard laboratory tests which are commonly done to check for other causes of Peripheral Neuropathy and other factors that influence the phenotype. All second tier testing should be completed as testing results are available.

7. Complete Blood Cell Count (CBC) with Differential

Results from the most recent CBC test should be reported.

Data Entry:

Normal: all measured parameters were within normal range
Abnormal: one or more parameters were **clinically significant** outside the normal range
ND/NA: Test was not performed during past 36 months or test results are not available.
Year of Test: calendar year test was performed. Must be within 36 months of visit.

8. Erythrocyte Sedimentation Rate (ESR)

Measures the rate red blood cells sediment in an anticoagulated blood tube within one hour, expressed in millimeter per hour (mm/h). The normal range values vary pending on the laboratory performing the testing. High ESR values are considered an indication for inflammation.

Data Entry:

Normal: sedimentation within normal limits
Abnormal: sedimentation elevated to clinical significance
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

9. Thyroid Stimulating Hormone (TSH)

Measures amount of Thyroid Stimulating Hormone (TSH) in blood reported in milli-International Units per Liter (mIU/L). The normal range may differentiate between laboratories and the range information provided by the laboratory which conducted the test should be consulted, however most common standard is 0.5-5 mIU/L.

Data Entry:

Normal: measured TSH level is within normal range
Abnormal: measured TSH level is outside of normal range – both hypo- and hyperthyroidism should be reported as abnormal
ND/NA: test was not performed within the last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
TSH value: measured TSH level should be entered in mIU/L.

10. Lipid Profile

Lipid profile or lipid panel is a series of blood tests that serves as an initial broad medical screening tool for abnormalities in lipids, such as cholesterol and triglycerides. Lipid profile is critical component for the evaluation of the presence of metabolic syndrome and should be obtained for all PNRR enrollments. If information is not available in the medical records, the study team shall contact the Primary Care Physician to obtain the information. Laboratory testing results for lipid profile should be reported in milligram per deciliter (mg/dL).

Data Entry:

Normal: all measured lipids were in the normal range
Abnormal: one or more measured lipids were outside of normal range (cholesterol ≥ 200 mg/dL, triglycerides ≥150 mg/dL, HDL <30 mg/dL for men or <40 mg/dL for women)
ND/NA: test was not performed within last 36 months or test results are not available.
Year of Test: calendar year test was performed. Must be within 36 months of visit.

If a Lipid Profile was created, the following values shall be entered:

- **Cholesterol:** measured cholesterol level in mg/dL
- **Triglycerides:** measured triglyceride level in in mg/dL

- **HDL:** measured HDL-cholesterol level in mg/dL
- **LDL:** measured LDL-cholesterol level in mg/dL

11. C-reactive protein (CRP)

Used as a screening test for inflammation - CRP levels rise in response to inflammation in serum. Normal range in healthy humans is usually defined as < 0.5 mg/L blood, but might vary pending on testing laboratory.

Data Entry:

Normal: CRP level within normal range
Abnormal: CRP level above normal range
ND/NA: test was not performed within last 36 months or test results are not available.
Year of Test: calendar year test was performed. Must be within 36 months of visit.

12. Anti-Nuclear Antibody (ANA) test

Also known as Antinuclear Factor or ANF. Test is used to diagnose lupus, Sjörgen's syndrome, rheumatoid arthritis, mixed connective tissue disease, polymyositis, dermatomyositis, autoimmune hepatitis and drug-induced lupus.

Data Entry:

Normal: negative, no ANA's found, titer <1:10
Abnormal: positive, one or more ANA's found, titer >1:10
ND/NA: test was not performed within last 36 months or test results are not available.
Year of Test: calendar year test was performed. Must be within 36 months of visit.

13.a Urine Immunofixation (UIFE) and/or

13.b Urine Electrophoresis (UPEP)

Screening for abnormal protein levels in urine. If Urine Immunofixation (UIFE) showed an abnormality, Urine Electrophoresis (UPEP) is required.

Data Entry:

Normal: monoclonal immunoglobulins are not found
Abnormal: monoclonal immunoglobulin(s) are detected
ND/NA: test was not performed within the last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

If Abnormal, report abnormality: _____

The abnormal finding from either UIFE and/or UPEP should be reported.

14. Methyl malonic acid (MMA)

Test used to diagnose early or mild Vitamin B12 deficiency. The normal range for MMA levels in blood can slightly vary between laboratories and the reference range information provided by the laboratory should be used to determine if a value is considered Normal or Abnormal.

Data Entry:

Normal: MMA level considered to be within normal range
Abnormal: elevated MMA levels above normal range
ND/NA: test was not performed within last 36 months or test results are not available.
Year of Test: calendar year test was performed. Must be within 36 months of visit.

THIRD TIER

INFLAMMATORY / AUTOIMMUNE:

15. Kappa / Lambda Light Chains

Test measures amounts of free kappa and free lambda immunoglobulin light chains in blood serum, and the ratio between kappa and lambda chains is calculated. If the concentration of either kappa or lambda chains is outside of the normal range, or if the kappa/lambda ratio is outside of the normal range, an abnormal test result should be reported.

Data Entry:

Normal: normal test results all evaluated parameters are within range
Abnormal: either kappa or lambda or K/L ratio are outside of normal range
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

16. Angiotensin-Converting-Enzyme (ACE) (serum)

Also referred to as Serum Angiotensin-Converting Enzyme (SACE)

Elevated levels of ACE are common in people with leprosy, hyperthyroidism, acute hepatitis, primary biliary cirrhosis, diabetes mellitus, multiple myeloma, osteoarthritis, amyloidosis, Gaucher disease, pneumoconiosis, histoplasmosis, miliary tuberculosis and it is used to diagnose sarcoidosis. Lower than normal ACE levels can indicate chronic liver disease, eating disorders, steroid therapy and therapy for sarcoidosis, or an underactive thyroid (hypothyroidism). The normal range for ACE levels varies between laboratories, thus the lab report should be consulted to determine if the test revealed a normal or abnormal result.

Data Entry:

Normal: measured ACE level in “normal” range
Abnormal: ACE levels are either higher or below normal range
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

17. Anti Double-Stranded DNA Antibodies (Anti ds-DNA Ab)

Screening test for lupus, rheumatoid arthritis, HIV and other autoimmune diseases.

Data Entry:

Normal: negative result for Anti ds-DNA Ab
Abnormal: positive result
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

18. Anti-Endomysial Immunoglobulin G antibodies

Screening test for autoimmune diseases, including celiac disease.

Data Entry:

Normal: negative result
Abnormal: positive result
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

19. Anti-Ganglioside Antibodies (GM-1)

Screening test for autoimmune neuropathies.

Data Entry:

Normal: negative screening result
Abnormal: positive screening result
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

20. Anti-Gliadin Antibodies (IgA / IgG)

Indication for gluten sensitivity. Anti-Gliadin IgA: present in 80% of people diagnosed with celiac disease and can be indicator for gluten-sensitive idiopathic neuropathy; Anti-Gliadin IgG: celiac disease and non-celiac gluten sensitivity.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

21. Anti-Neutrophil (p-ANCA and c-ANCA)

Screening test for autoimmune diseases, particularly vasculitis

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

22. Anti-RO (SSA) Antibodies & Anti-LA (SSB) Antibodies

The screening test is widely used to identify patients with Sjögren's syndrome and/or systemic lupus erythematosus (SLE). But Anti-Ro SSA Antibodies are also present in patients with other autoimmune diseases, and both need to be elevated for positive diagnosis for Sjögren's. SSA testing is sometimes referred to as Ro52 or Ro60 testing.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test for either SSA or SSB antibodies or both
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

23. Anti-68 Kd Antibody (cochlear antigen)

Screening test for sensorineural hearing loss (SNHL), commonly referred to as nerve deafness.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

24. Anti-MAG Dual Antigen (elisa-ather)

Screening test for peripheral neuropathy caused by IgM monoclonal gammopathy with high anti-MAG titers with purely sensory or mixed sensory and motor neuropathy and predominantly demyelinating features.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

25. Anti-Parietal Cell Antibodies

Screening test that looks for antibodies against the parietal cells of the stomach. Parietal cells are critical for human body to absorb vitamin B12 from food.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

26. Anti-Thyroglobulin Antibodies

Screening test for thyroid antibodies, usually ordered to diagnose an autoimmune thyroid disease or thyroid dysfunction.

Data Entry:

Normal: negative test
Abnormal: positive test (antibodies found)
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

27. Rheumatoid Factor (RF)

Screening test, measuring the amount of Rheumatoid Factor (RF) present in serum. Used as a diagnostic test for rheumatoid arthritis and Sjörgen's syndrome. The reference range of the testing laboratory should be consulted to determine if the test result is considered normal or abnormal.

Data Entry:

Normal: low levels of RF
Abnormal: elevated levels of RF detected
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

28. Tissue Transglutaminase Immunoglobulin A (IgA) Antibodies

Screen for autoantibodies against transglutaminase protein, which are found in patients with celiac disease, juvenile diabetes, inflammatory bowel disease and various forms of arthritis.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

29. Cryoglobulins

Screening for vasculitis and other autoimmune diseases.

Data Entry:

Normal: negative screen
Abnormal: positive screen
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

INFECTIOUS:

30. Human Immunodeficiency Virus (HIV) screen

Screening test for HIV antibodies. For patients with positive HIV test, the first positive HIV test should be reported. 36 months limitation does not apply to HIV testing.

Data Entry:

Normal: negative screen
Abnormal: positive screen
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

31. Lyme screen

Screening test for *Borrelia burgdorferi* antibodies.

Data Entry:

Normal: negative screen
Abnormal: positive screen, must also be confirmed by Western Blot Test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

32. Rapid Plasma Reagin Antibodies (RPR Ab)

Screening test for syphilis.

Data Entry:

Normal: negative screen
Abnormal: positive screen
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

33. Hepatitis B screen

Screening test for Hepatitis B antibodies.

Data Entry:

Normal: negative screen or positive screen due to vaccinations
Abnormal: positive screen
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

34. Hepatitis C screen

Screening test for Hepatitis C antibodies

Data Entry:

Normal: negative screen (non-reactive)
Abnormal: positive screen (reactive)
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

GENETIC:

35. Galactosidase Assay

Screen test for Fabry's disease.

Data Entry:

Normal: negative screen
Abnormal: positive screen
ND/NA: test was not performed, or test results are not available
Year of Test: calendar year test was performed (no time limit for genetic testing).

36. Charcot-Marie-Tooth (CMT) panel genetic testing

Genetic testing results screening for inherited forms of polyneuropathy. 36-months limitation does not apply for genetic testing results. If patients are diagnosed with CMT, their enrollment category should be changed to "Other" in the PEF, as they are no longer eligible enrollments.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test (confirmation of CMT)
ND/NA: genetic screening test was never done
Year of Test: calendar year test was performed (no time limit for genetic testing).

PARANEOPLASTIC:

37. Anti-Ri antibody screen

Screening test for autoantibodies against neuronal nuclei of the central nervous system.

Data Entry:

Normal: negative screen
Abnormal: positive screen (antibodies present)
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

38. Anti-Hu antibody screen

Antineuronal Nuclear Antibody (Anti-Hu) screening test. Anti-Hu is associated with subacute syndrome of encephalomyeloradiculopathy, sensory neuropathy, and autoimmune neuropathy, predominantly affecting the gastrointestinal tract, and can also indicated small cell carcinoma of the lung.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months of visit.

39. Anti-Purkinje Cell (YO) antibody screen

Screening test for Neuronal Nuclear antibodies affecting Purkinje nerve cells.

Data Entry:

Normal: negative screening test
Abnormal: positive screening test
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

40. Paraneoplastic Panel (MAYO)

Screening for autoantibodies in blood, including Anti-Hu, -Ri and –Yo plus others. For patients who received chemotherapy, a negative Paraneoplastic Panel is considered a confirmation that the neuropathy is caused by chemotherapy drugs.

Data Entry:

Normal: negative result
Abnormal: positive result (autoimmune antibodies present)
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

If Abnormal, list antibodies: _____

All antibodies for which abnormal levels were measured should be listed.

ANN1S	Anti-Neuronal Nuclear Ab, Type 1
ANN2S	Anti-Neuronal Nuclear Ab, Type 2
ANN3S	Anti-Neuronal Nuclear Ab, Type 3
AGN1S	Anti-Glial Nuclear Ab, Type 1
PCABP	Purkinje Cell Cytoplasmic Ab Type 1
PCAB2	Purkinje Cell Cytoplasmic Ab Type 2
PCATR	Purkinje Cell Cytoplasmic Ab Type Tr
AMPHS	Amphiphysin Ab, S
CRMS	CRMP-5-IgG, S
STR	Striational (Striated Muscle) Ab, S
CCPQ	P/Q-Type Calcium Channel Ab
CCN	N-Type Calcium Channel Ab
ARBI	ACh Receptor (Muscle) Binding Ab
GANG	AChR Ganglionic Neuronal Ab, S
VGKC	Neuronal (V-G) K+ Channel Ab, S
OTHER	Other:_____

OTHER:

41. Creatine Kinase (CK)

Also referred to as creatine phosphokinase (CPK) is a screen test for inflammation, particularly myositis. CK levels of 24-204 IU/L are generally regarded as normal. Elevated CK levels are associated with several clinical diagnosis.

Data Entry:

Normal: CK levels within normal range
Abnormal: CK levels outside of normal range
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

42. Homocysteine

Elevated homocysteine levels can be an indicator for low B-vitamin intakes. The normal range may vary between laboratories, and the reference information should be consulted to determine if the homocysteine levels are within normal limits or not. Low homocysteine levels should not be reported as abnormal in PNRR.

Data Entry:

Normal: within normal range
Abnormal: elevated level
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

43. Urine Heavy Metals

Screen for heavy metals in urine.

Data Entry:

Normal: negative (no elevated levels of heavy metals detected in urine)
Abnormal: positive for one or more heavy metals
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

44. Vitamin E

Vitamin E deficiency is a known cause for peripheral neuropathy. Normal ranges vary between laboratories and the provided references should be consulted to determine if the measured Vitamin E levels are within normal range or low. Only Vitamin E deficiencies should be reported as an abnormal result. Testing results should be reported in milligram per liter (mg/L). Lab testing results reported in µg/mL or any other units should be converted to mg/L before entered into REDcap.

Data Entry:

Normal: Vitamin E levels in normal range or elevated

Abnormal: Vitamin E levels below normal range
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Vitamin E value: measured Vitamin E value should be entered in mg/L

45. Vitamin B1 (Thiamin)

Vitamin B1 deficiencies should be reported as abnormal test result. High values should **not** be reported as abnormal in the PNRR database. Vitamin B1 is usually measured in nanomole per liter (nmol/L) but some laboratories report their results in microgram per deciliter (µg/dL). The normal range is generally 74-222 nmol/L or 2.5-7.5 µg/dL. For PNRR, laboratory testing reported in ug/dL should be converted to nmol/L before the value is entered into REDcap.

Data Entry:
Normal: Vitamin B1 within normal range or elevated
Abnormal: Vitamin B1 deficiency
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Vitamin B1 value: enter measured Vitamin B1 level in nmol/L

46. Vitamin B6

Vitamin B6 is involved in the formation of myelin and both B6 deficiency and chronically elevated B6 levels can cause neuropathy, and both conditions should be reported as abnormal in the database. B6 testing results are either reported as nanogram per milliliter (ng/mL), microgram per liter (µg/L) or deciliter (µg/dL), or in nanomole per litter (nmol/L). Normal Vitamin B6 ranges from 5.3-46.7 ng/mL. Vitamin B6 testing results should be reported in ng/mL and test results reported in µg/L, µg/dL or nmol/L should be converted into ng/mL before data is entered.

Data Entry:
Normal: Vitamin B6 level are within normal range
Abnormal: Vitamin B6 levels are either elevated or below normal range.
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.
Vitamin B6 value: enter measured Vitamin B6 value in ng/mL

AUTONOMIC:

47. Quantitative Sudomotor Autonomic Reflex Test (QSART)

Test measures the autonomic nerves that control sweating. The test is useful in assessing autonomic nervous system disorders, peripheral neuropathies and some types of pain disorders.

Data Entry:
Normal: normal sweating response

Abnormal: elevated sweating response
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

48. Tilt Table

Used to evaluate the cause of unexplained fainting (syncope)

Data Entry:
Normal: not syncope
Abnormal: syncope or pre-syncope
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

49. Sweat Testing

Results from Thermoregulatory Sweat Test (TST) should be reported here. TST evaluates the patient's ability to sweat when stimulated by a warm and humid environment. This test assesses both the central and peripheral autonomic nervous system's control of sweating and body temperature regulation (thermoregulation). Both reduced sweating (anhidrosis) and excessive sweating (hyperhidrosis) patterns shall be reported as abnormal.

Data Entry:
Normal: normal sweating pattern
Abnormal: abnormal sweating pattern detected
ND/NA: test was not performed within last 36 months or test results are not available
Year of Test: calendar year test was performed. Must be within 36 months of visit.

BIOPSIES:

50. Nerve biopsy

Nerve biopsy was performed on one or multiple nerves. If a nerve biopsy has been conducted, the result should be reported here. There is no timeframe limitation for nerve biopsy results.

Data Entry:
Normal: no abnormalities were detected
Abnormal: abnormalities were present
ND/NA: no nerve biopsy was previously performed
Year of Test: calendar year test was performed.

51. Lip biopsy (Sjögren's)

Diagnostic test for Sjörgen's syndrome. Lip biopsy results for other diagnosis such as for malignant cancer should not be reported. There is no timeframe limitation for lip biopsy results.

Exhibit E
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Data Entry:

Normal: negative for Sjörgen's syndrome
Abnormal: positive for Sjörgen's syndrome
ND/NA: no lip biopsy was previously performed.
Year of Test: calendar year test was performed

Date Data Entry Completed:

Date should be entered when data entry was completed.

Nerve Workup Form (PNW) Status:

- **Incomplete:** not all data is entered yet
- **Unverified:** data is entered, but not verified
- **Complete:** all information is verified, no additional edits are anticipated