

Exhibit E
PNRR 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 prior and within 12 months after enrollment should be reported in the PNW form, with the exception of genetic tests.

The FIRST TIER testing is considered the Minimum Data Set and must be provided for all PNRR subjects. It is acceptable to report the results from testing conducted outside of the enrollment centers in the PNW form.

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 is waived at the physician's discretion when it is clear that the neuropathy does not involve larger nerve fibers.

If a patient had NCS testing earlier than 36 months prior to visit, the NCS interpretation should 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

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

For patients who have a normal NCS/EMG result, a skin biopsy is requested.

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 up to 36 months prior and 12 months after visit. Results from the most recent skin biopsy should be reported if the patient had more than one skin biopsy.

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

Results from the most recent Comprehensive Metabolic Panel (CMP) should be reported.

Data Entry:

Normal: creatinine value is within normal range

Abnormal: creatinine value is outside the normal range

ND/NA: no Chemistry panel was not done, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Creatinine level: enter measured creatinine value in milligram per deciliter (mg/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) as the cause of neuropathy.

a. Glycated Hemoglobin (HgA1C)

The glycated hemoglobin value is an indicator for diabetes mellitus. The border value can slightly vary between laboratories, and the reference range information should be used to determine if value is normal or abnormal.

Data Entry:

Normal: measured value was within the reference range

Abnormal: measured value was **higher** than the reference 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 prior or 12 months after visit.

HgA1C Level: enter measured HgA1C level in % (of total hemoglobin)

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b. Blood Glucose (fasting)

Expresses the amount of glucose in blood after a minimum of 8 hour fasting.

Note: study coordinator should verify that the patient was truly fasting.

Data Entry:

Normal: test result within normal range

Abnormal: fasting blood glucose levels were outside the normal range

ND/NA: test was not performed

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Fasting Glucose level: fasting glucose level in milligram per deciliter (mg/dL)

c. Oral Glucose Tolerance test

Measured blood glucose levels after two (2) hours should be reported as normal or abnormal. Both higher (hyperglycemic) and lower (hypoglycemic) results should be reported as abnormal.

Data Entry:

Normal: test result within normal range

Abnormal: blood glucose levels after 2 hours were outside the normal range

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Glucose level: 2-hour glucose level should be entered in milligram per deciliter (mg/dL)

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

5.b Serum Protein Electrophoresis (SPEP)

Both tests evaluate immunoglobulin (antibodies) and protein levels in serum. If Serum Immunofixation (SIFE) results in abnormal result, 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 test results are not available

Year of Test: calendar year test was performed; must be within 36 months prior or 12 months after visit.

If IFE and/or SPEP were abnormal:

Identification of type of abnormality:

- **Monoclonal gammopathy:** presence of paraprotein(s), one or more immunoglobulins are light chains are marked as abnormal elevated. Polyclonal gammopathies should be reported as monoclonal gammopathies.
- **Hypoglobulinemia:** hypoproteinemia, one or more immunoglobulins or light chains are marked as abnormal low

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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. Only values below the normal range should be reported as abnormal. High values are of little concern and are common in patients who take Vitamin B supplements and should not be reported as abnormal.

Data Entry:

Normal: Vitamin B12 values in normal range or elevated

Abnormal: Vitamin B12 value is below normal range (200 pg/mL)

ND/NA: test was not performed or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Vitamin B12 Value: enter measured Vitamin B12 value in picogram per milliliter (pg/mL)

SECOND TIER

The Second Tier lists standard laboratory tests which are commonly used to diagnose the cause for Peripheral Neuropathy.

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 or test results are not available.

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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.

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Data Entry:

Normal: sedimentation within normal limits

Abnormal: sedimentation elevated to clinical significance

ND/NA: test was not performed or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

9. Thyroid Stimulating Hormone (TSH)

Measures amount of Thyroid Stimulating Hormone (TSH) in blood. The normal range may differentiate between laboratories and the range information provided by the laboratory which conducted the test should be consulted.

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

ND/NA: test was not performed or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

TSH value: measured TSH level in milli-International Units per liter (mIU/L)

10. Lipid Profile

Lipid profile or lipid panel is a series of blood tests and the standard medical screening test for lipid levels in the blood.

Data Entry:

Normal: all measured lipids were in the normal range

Abnormal: one or more measured lipids were outside of normal range

ND/NA: test was not performed or test results are not available.

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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

- **Cholesterol:** measured cholesterol level in milligram per deciliter (mg/dL)
- **Triglycerides:** measured triglyceride level in milligram per deciliter (mg/dL)
- **HDL (high density lipids):** measured HDL level in milligram per deciliter (mg/dL)
- **LDL (low density lipids):** measured LDL level in milligram per deciliter (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.

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Normal: CRP level within normal range

Abnormal: CRP level above normal range (elevated)

ND/NA: test was not performed, or test results are not available.

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

12. Anti-Nuclear Antibody (ANA) test

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

Data Entry:

Normal: negative, no ANA's are detected

Abnormal: positive, one or more ANA's are detected

ND/NA: test was not performed or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit

13.a Urine Immunofixation (IFE) and/or

13.b Urine Electrophoresis (UPEP)

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

Data Entry:

Normal: monoclonal immunoglobulins are not detected

Abnormal: monoclonal immunoglobulin(s) are detected

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available.

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Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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 calculates the ratio between kappa and lambda chains. This test is complementary to SIFE/SPEP, because it determines the exact concentrations while SIFE/SPEP only determine if the amount of light chains in the blood is normal or abnormal.

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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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 screening

Abnormal: positive result, Anti ds-DNA Ab are present

ND/NA: test was not performed, or test results are not available

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Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

18. Anti-Endomysial Immunoglobulin G antibodies

Screening test for autoimmune diseases, including celiac disease.

Data Entry:

Normal: negative result, no antibodies found

Abnormal: positive result, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

19. Anti-Ganglioside Antibodies (GM-1)

Screening test for autoimmune neuropathies.

Data Entry:

Normal: negative screening result, no antibodies found

Abnormal: positive screening result, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

20. Anti-Gliadin Antibodies (IgA / IgG)

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

Data Entry:

Normal: negative screening test, no antibodies found

Abnormal: positive screening test, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

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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 auto-immune diseases, and both need to be elevated for positive diagnosis for Sjögren's.

Data Entry:

Normal: negative screening test, no antibodies found

Abnormal: positive screening test, SSA and/or SSB antibodies are present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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

Screening test for peripheral neuropathy with purely sensory or mixed sensory and motor neuropathy with predominantly demyelinating features.

Data Entry:

Normal: negative screening test

Abnormal: positive screening test

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, no antibodies found

Abnormal: positive screening test, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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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, no antibodies found

Abnormal: positive test, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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 Sjörger'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 in blood

Abnormal: elevated levels of RF detected

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, no antibodies found

Abnormal: positive screening test, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

29. Cryoglobulins

Screening for vasculitis and other auto-immune diseases.

Data Entry:

Normal: negative screen, no cryoglobulins found

Abnormal: positive screen, cryoglobulins present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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INFECTIOUS:

30. Human Immunodeficiency Virus (HIV) screen

Screening test for HIV antibodies.

Data Entry:

Normal: negative screen, no HIV viruses found

Abnormal: positive screen, HIV viruses detected

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Negative HIV screening tests should only be reported when performed within 36 months prior or 12 months after visit. All positive HIV screening tests should be reported, independent of the year they were performed.

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 or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

32. Rapid Plasma Reagin Antibodies (RPR Ab)

Screening test for Syphilis.

Data Entry:

Normal: negative screen, no RPR antibodies found

Abnormal: positive screen, RPR antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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

Screens for known genotypes associated with CMT.

Data Entry:

Normal: negative screening test

Abnormal: positive screening test (confirmation of CMT)

ND/NA: genetic screening test was not performed, or test results are not available

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, no antibodies found

Abnormal: positive screen, antibodies present

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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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 indicate small cell carcinoma of the lung.

Data Entry:

Normal: negative screening test

Abnormal: positive screening test

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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

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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). Screen test for inflammation, particularly myositis. 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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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.

Data Entry:

Normal: Vitamin E levels in normal range or elevated

Abnormal: Vitamin E levels below normal range

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Vitamin E value: measured Vitamin E value should be entered in milligram per liter (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.

Data Entry:

Normal: Vitamin B1 within normal range or elevated

Abnormal: Vitamin B1 deficiency

ND/NA: test was not performed, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Vitamin B1 value: enter measured Vitamin B1 level in nanomol per liter (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.

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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

Vitamin B6 value: enter measured Vitamin B6 value in nanogram per milliliter (ng/mL)

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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 or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after 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, or test results are not available

Year of Test: calendar year test was performed. Must be within 36 months prior or 12 months after visit.

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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. No time limit for nerve biopsies.

51. Lip biopsy (Sjögren's)

Diagnostic test for Sjögren'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.

Data Entry:

Normal: negative for Sjögren's syndrome

Abnormal: positive for Sjögren's syndrome

ND/NA: no lip biopsy was previously performed.

Year of Test: calendar year test was performed. No time limit for lip biopsies.

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