Precipio Pathology Services

Problem

- Cancer misdiagnosis in hematopoietic malignancies is occurring at alarming rates of up to 25%. [1]
- Blood-related cancers consist of over 300 sub-classifications and are associated with the highest rate of misdiagnosis. [2]

1 IN 4 PATIENTS IS MISDIAGNOSED

1 https://ascopubs.org/doi/abs/10.1200/JCO.2010.31.2223
2 Lokuhetty, Dilani. WHO Classification of Tumours. International Agency for Research on Cancer, 2019.

Precipio is a CLIA/CAP certified laboratory specializing in hematopathology, and our vision is to eradicate the problem of misdiagnosis. Our solution addresses three fundamental flaws in the diagnostic industry, resulting in **99% diagnostic accuracy.**

Industry Flaw

Differential Prerequisite

Archaic Lab Technologies

Shortage in Pathology Sub-Specialization

Precipio's Solution

Omnia™

- Insurance companies typically require the clinician to identify their clinical suspicion as the key driver of testing. However, an incorrect clinical suspicion can lead the lab down the wrong path.
- Omnia's proprietary algorithm incorporates clinical history, CBC, and other inputs to form the correct clinical question, increasing the likelihood of arriving at an accurate diagnosis.
- In approximately 40% of Precipio's cases, Omnia arrives at a different clinical question from the clinician's. This ensures the laboratory tests for the relevant disease, reducing the possibility for diagnostic error.

Proprietary Technologies

Precipio's proprietary technologies reduce diagnostic error and improve patient care:

HEMESCREEN® : hematologic screening panel with rapid turnaround time.

IV-Cell : cytogenetics culture media that reduces the occurrence of false negative results.

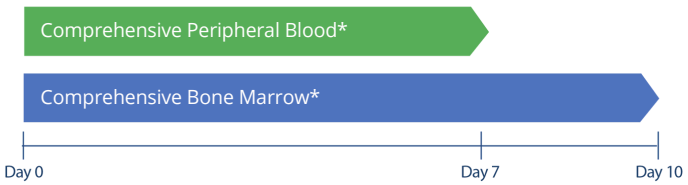
Rev-CI : proprietary cell enrichment process enabling conclusive FISH results.

Sub-Specialized Expertise

- Cases are assigned to a sub-specialized expert hematopathologist to ensure a match between the clinical assessment of the patient and the pathologist's expertise.
- The expert oversees testing to ensure only medically necessary tests are performed.

Diagnostic Accuracy

Comprehensive Diagnosis: 7-10 Business Days



Turnaround time may vary due to case complexity.

Precipio, Inc.
4 Science Park, New Haven, CT 06511 203.787.1717

PRECIPIO EXPECT MORE.

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PRECIPIO
203-787-1717
203-901-1289

COMPREHENSIVE REPORT

Patient: John A. Doe
DOB/Gender: 10/10/44 (74 yrs) - Male
Patient ID/MRN: 123456
Date Collected: 06/17/2021

Case#/Status: X**21**-00**323** - Final
Report Category:
Neoplastic

Provider: Jane Smith, M.D.
Hematology Oncology Associates
Tel: 800-123-4567
Fax: 800-765-4321

DIAGNOSIS

1. High grade myeloid neoplasm, Myelodysplastic Syndrome with Excess Blasts Type 2 (MDS-EB2).
2. Low level kappa monoclonal B cell lymphocytosis. See comment.

COMMENT

The bone marrow findings are consistent with involvement by a high grade myeloid neoplasm with approximately 15% blasts, consistent with MDS-EB2 utilizing current WHO criteria for myeloid neoplasms. The blast percentage in the core biopsy is variable, and focally approaches 20%. This could suggest early transformation to acute myeloid leukemia. This sample is positive for IDH2 mutations. The sample also shows low level kappa monoclonal B cell lymphocytosis (5 to 10% of sample) of uncertain clinical significance. Clinical correlation is recommended. See below for summary of testing results for this sample.

All myeloid and lymphoid neoplasms are now classified and named in accordance with the newly revised 2017 version of the WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues.

COMPONENT DIAGNOSES

Biopsy: Bone marrow biopsy showing dysplastic hematopoiesis and increased blasts, approximately 15% of cellularity, consistent with a high grade myeloid neoplasm, Myelodysplastic Syndrome with Excess Blasts Type 2 (MDS-EB2).

Aspirate: Bone marrow aspirate showing: (1) increased blasts of myeloid phenotype consistent with involvement by a high grade myeloid neoplasm and (2) small lymphocytosis with immunophenotypic features consistent with involvement by B cell lymphoma. See comment.

Flow Cytometry: 1. Immunophenotypic features of an expanded myeloid blast population, 12% of sample, consistent with involvement by a high grade myeloid neoplasm.
2. Expanded population of kappa monoclonal B cells, 20% of sample, consistent with involvement by B cell non-Hodgkin lymphoma.

Karyotyping: No evidence of an acquired clonal abnormality, see interpretation below.

FISH: No evidence of an acquired clonal abnormality, see interpretation below.

Molecular: HemeScreen AML results reveal:
- Negative for IDH1 mutations
- Negative for FLT3 mutations
- Negative for KIT mutation
- Positive for IDH2 mutations
- Negative for NPM1 mutations
- Negative for CEBPA mutations* see comment

CLINICAL DATA

ICD-10: C85.90, D72.819, N18.31, E11.9, D63.1, D64.9, Z13.79. Non-Hodgkin lymphoma, unspecified, unspecified site. Leukocytopenia, unspecified. Chronic kidney disease, stage 3a. Type 2 diabetes mellitus without complications. Anemia in chronic kidney disease. Anemia, unspecified. New diagnosis.

Received CBC, reported on 06/17/2021: WBC 2.2; RBC 3.72; HGB 10.4; HCT 32.3; MCV 87; MCH 28.0; MCHC 32.2; RDW 14.3%; PLT 154; LYM 65%; MON 12%; NEU 19%; EOS 3%; BAS 1%

Electronically Signed By: Frank Bauer, MD, Precipio, Inc. (06/28/21 16:00)

Patient: John A. Doe
Case #: X21-00323
Received Information: 1 Formalin containers, 5 smears, 4 touch preps, 1 green-top tube, 1 lavender-top tube
Received: 06/18/21 13:00
Reported: 06/28/21 14:00