Lab Dept: Anatomic Pathology

Test Name: CLONOSEQ

General Information

Lab Order Codes:	CLSEQ
Synonyms:	clonoSEQ
CPT Codes:	n/a – not institutionally billed
Test Includes:	Next-generation sequencing to identify dominant sequences from the patient's cancer cells, monitor dominant trackable DNA sequences identified by the Clonality (ID) Test and/or detect any newly emerging sequences.

Logistics

Test indications:	Molecular detection of measurable blood cancer minimal residual disease (MRD) throughout treatment. Options include a clonality (ID) test and tracking (MRD) test.
Lab Testing Sections:	Anatomic Pathology - Sendouts
Referred to:	Adaptive Biotechnologies (ADPT)
Phone Numbers:	MIN Lab: 612-813-6280 STP Lab: 651-220-6550
Test Availability:	Daily, 24 hours
Turnaround Time:	Clonality ID results within 14 days, MRD Tracking results within 7 days of specimen receipt at reference lab

Special Instructions:	Ordering provider must complete the test requisition form by logging into the clonoSEQ ordering portal. The requisition form MUST be printed and sent to Children's Minnesota Sendouts Lab with the specimen or as soon as possible after collection. Specimens will not be shipped without the completed form. Ordering clonoSEQ - clonoSEQ This orderable test is ONLY available in the outpatient setting and the ordering provider MUST obtain and record patient insurance information on the test request form (i.e., Adaptive performs 3rd party billing, no charge back to Children's Minnesota). Sendouts note: if this is ordered as institutional billing, confirm that is correct with the ordering provider, then cancel and reorder as MBAT if so. Pricing information would need to be obtained from the reference lab.

Specimen

Specimen Type:	Blood, bone marrow aspirate or slides
Container:	EDTA lavender top tube
Draw Volume:	Blood: 2-3 mL Bone marrow aspirate: 1-2 mL
Processed Volume:	Same as collection volume
Collection:	**Blood:** Collect 2-3 mL in EDTA Lavender top **Bone marrow aspirate:** Collect 1-2 mL aspirate in a DRY syringe then immediately transfer to an EDTA lavender top vacutainer, inverting several times to mix anticoagulant with the specimen to prevent clotting. See website for further details on other acceptable specimens (e.g., slides) https://www.clonoseq.com/resources-and-support/
Special Processing:	Lab Staff: Do not centrifuge blood or bone marrow aspirate. Sendouts: Ship overnight at room temperature. If same-day shipping isn't possible, store refrigerated, then ship ambient to arrive within 7 days of collection. If not refrigerated, bone marrow specimens are stable ambient for up to three days, blood for 5 days. See the Adaptive ClonoSEQ requisition form for their FedEx account number and other information.
Patient Preparation:	N/A
Sample Rejection:	Blood specimens collected in incorrect anticoagulant; bone marrow aspirate collected in heparin syringe

Interpretive

Reference Range:	See interpretive report
Critical Values:	N/A
Limitations:	A successful Clonality ID test is required before an MRD test can be completed. ALL and CLL • MRD values obtained with different assay methods may not be interchangeable due to differences in assay methods and reagent specificity. • The results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings. • The clonoSEQ Assay is for use with specimens collected in EDTA tubes. • Results may vary according to sample time within the course of disease or by sampling site location. • The assay may overestimate MRD frequencies near the limit of detection (LoD). • The MRD frequency LoD varies based on the amount of gDNA that is tested and using lower gDNA input may prevent MRD detection at low frequencies. • Sample processing and cell enrichment strategies may affect the measured MRD frequency. • The volume and cellularity of sampled input material may affect the ability to detect low levels of disease. • False positive or false negative results may occur for reasons including, but not limited to: contamination; technical and/or biological factors such as the type of rearrangement or the size of the junction region. • The assay has been validated with the Illumina NextSeq 500 and 550. For CLL • MRD is based on measurements of tumor cells detected in peripheral blood and/or bone marrow. However, patients may have significant residual disease in unassessed compartments and U-MRD in one compartment cannot fully rule out the presence of disease in the other compartment, for example, U-MRD in blood may not be the same in bone marrow. Therefore assessment of MRD in CLL should employ a multimodal approach including clinical examination, patient medical history, and other findings. • Outcome for patients with MRD detectable in bone marrow but not in peripheral blood (PB-/BM+) may differ according to type of therapy. • This assay is capable of monitoring specific tumor clonotypes. The association between MRD assessments and patient clinical status for the purpose of monitoring changes in disease (e.g., relapse, remission, stable disease) has not been demonstrated. • The value of MRD in CLL for previously untreated or “watch and wait” patients is not established. • CLL is a heterogeneous disease. MRD values and expectations for outcome may not be generalizable across treatments. Changes in MRD should be interpreted with caution when used to evaluate disease burden in therapies that have not been validated. • Regardless of MRD status, cytogenetics play an independent role in patient risk status and its impact on PFS/OS.
Methodology:	Next-generation sequencing (NGS)
References:	clonoSEQ MRD Test (October 2024)
Updates:	Initial entry: 10/29/2024