

Molecular In My Pocket™ ...

Key Elements for Effective Reporting of Molecular Diagnostic Tests

Molecular diagnostic reports should be clear and succinct. Both actionable and critical information should be visible on the first page of the report. Ideally, this is achieved in a table with high-level interpretation. The information should also be clear to a generalist clinician without expertise in molecular diagnostics.

The necessary components of molecular diagnostic reports are listed in the following sections.

✓ Requisition Information:

- Patient identifier: name, medical record number, date of birth
- Ordering physician
- Indication for testing
- Specimen accession number from submitting lab (if performing referral testing)
- Specimen source and type
- Collection date and time
- Other pertinent information for testing, such as ethnicity or gender/biological sex, may be included in the report

✓ Primary Clinically Significant Results:

- Table or brief list of clinically relevant variants with diagnostic, therapeutic, or prognostic value
- If appropriate, indicate the relevant Tier 1, Tier 2, and Tier 3 status for cancer variants
- A brief interpretation highlighting the clinical significance should be provided as well as any pertinent comments
- Clinical management recommendations whenever appropriate (e.g., referral, genetic counselor follow up, further testing)
- Use standardized naming (HGVS Nomenclature) and unequivocal variant descriptions (including transcript IDs and/or genomic descriptions)

✓ Additional Clinically Relevant Results:

- These include results for which there may not be treatment but that may have additional relevant interpretation

- Include brief interpretation as appropriate. This could include variant of unknown significance (VUS) and clinical trial associations
- ✓ **List of All Genes Tested, Including Those with “Negative” Results**
- ✓ **Comment Section to Include the Following Clinically Relevant Information:**
 - A more-detailed description of the clinically relevant, potentially relevant, or VUS genes, with a comprehensive explanation of each gene and its associations with specific condition(s)
- ✓ **Genes with Insufficient Coverage**
 - Specific issues with the specimen or testing that impacted quality of results and/or interpretation
- ✓ **Detailed Information on Testing Methods and Genomic Targets Examined**
 - Specify the reference genome used
 - Information on reagents and equipment
 - Information on bioinformatics tools used, including the pipeline version
 - Analytic performance characteristics
 - Reference ranges, as appropriate
 - Limitations and disclaimers
- ✓ **Appropriate References**
- ✓ **Other elements:**
 - Date of the report
 - Test performed
 - Any changes between preliminary, final, or addendum/revised reports
 - If any part of testing was sent to a reference laboratory
 - Printed name of laboratory director
 - Name and address of testing lab
 - CPT and ICD10 codes may be included for billing purposes but are not required



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