Prepared by the Association for Molecular Pathology Training and Education Committee
For more educational resources, see: www.amp.org/AMPEducation
This reference card was developed as part of our Lab Management Series, available at: www.amp.org/LabManagement

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 in the first page of the report. Ideally this is achieved in table form 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/brief list of clinically relevant variants with diagnostic, therapeutic and/or prognostic value including the use of standard nomenclature
- 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 (referral, genetic counselor follow up, further testing)

✓ Additional Clinically Relevant Results:

- These include results for which there may not be treatment but may have additional relevant interpretation
- Include brief interpretation as appropriate. This could include 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 comprehensive explanation of each particular gene and data on associations with the specific condition(s).
- Ensure use of standardized nomenclature (HGVS) and unequivocal variant descriptions (including transcript IDs and/or genomic descriptions)

✓ 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

- Information on reagents, equipment and bioinformatics tools used
- Analytic performance characteristics
- Reference ranges as appropriate
- Limitations and disclaimers

✓ Appropriate References

✓ Other elements:

- 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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