

Open

Fluke test report format



Mehta Diagnostic And Research Centre

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Test	LIVER FUNCTION TEST	Result	Normal Range
Total Bilirubin (Unconjugated & Conjugated)	100 mg/dL	0.2 to 1.0 mg/dL	
Total Direct	100 mg/dL	0.1 to 0.6 mg/dL	
Total Indirect	100 mg/dL	0.1 to 0.4 mg/dL	
S.G.P.T. (ALT) (Kinetic)	1000 U/L	0 to 40 U/L	
S.G.O.T. (AST) (Kinetic)	1000 U/L	5 to 35 U/L	

Remark : Test done on semiauto biochemistry analyzer ERBACHEM V2.

End of Report

Dr Darshita Shah
M.D. (Patho.)

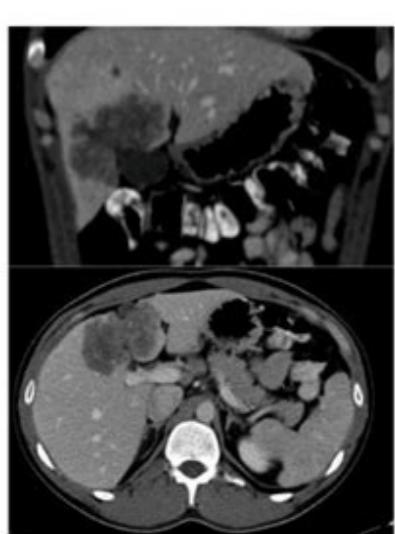


Case report

A 29-year-old male patient without any medical history was incidentally diagnosed with a giant hepatic mass during laparoscopic appendectomy (intra-operative biopsy revealed cholangiocarcinoma).

Blood test showed normal liver function with elevation of Ca19-9 (~264 ng/mL, normal value <35 ng/mL).

A thoracic and abdominal CT scan showed a heterogeneous mass of 8 x 5 cm in segment IVa-V with satellite nodule of 1 cm (Figure 1-2) and absence of extra-hepatic disease.



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ERCC Case Report

Final Case Report

Report Date: [REDACTED]

Report ID: [REDACTED]

Report Type: [REDACTED]

Report Status: [REDACTED]

Report Version: [REDACTED]

Report Description: [REDACTED]

Report Summary: [REDACTED]

Report Details: [REDACTED]

Report Conclusion: [REDACTED]

Report Signature: [REDACTED]

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On this page: Test Reports çAAW whenever biocompatibility or chemical characterization testing information is included in a submission, the FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided.çAAA Note: çAAAThe ISO 10993 series of standards do not specify either a method or test outcome, because these standards are both compendia and guidance. As such, these standards allow one to select different tests and methods, and do not necessarily include acceptance criteria.çAAA For example, the test report for hematology testing per ASTM F756 should include a description of the test, blank, positive, and negative supernatant conditions, in addition to the absorbance and percent hemolysis data.çAAA çAAAFor any test in which the results indicate a potential toxicity, the report should include a discussion of any test-specific issues that might have affected results.çAAA The test report should describe the conclusions drawn from the test results.çAAIf the test uses extracts, the report should explain how those extracts were prepared, and indicate the appearance of the extract (color, cloudy versus clear, and presence of particulates).çAAA Note: As discussed in ISO 10993-1:2018, any justification should include a risk analysis, which çAAAbegins with identification and characterization of the indirect and direct@ Atissue-contacting materials and components of the medical device. It has been FDA@As experience that test reports often address this, and raw data is usually not necessary. If the method used is not in a published document or FDA-recognized standard, a complete description of the method should be provided. If the test method is not in accordance with a published guidance document or FDA-recognized standard that includes defined acceptance criteria, a rationale for the acceptance criteria should be provided.çAAA Analysis of Results çAAA The test report should provide a summary of the test results and include tables with each data point.çAAA (for example, absorbance values, grades, representative images) çAAAnd statistical analyses.çAAA if applicable. Test reports should address the reporting provisions of any referenced standards, as well as the information outlined below.çAAA Test Article Preparation çAAAAs described in Section V.çAAAs of the FDA@As Biocompatibility Guidance on Use of ISO 10993-1.çAAA The test report should identify the test specimen; if the test article is not the medical device in its final finished form, a justification for the test article used should be provided either in the test report or in the submission to FDA.çAAA (See Attachment F of the FDA@As Biocompatibility Guidance on Use of ISO 10993-1, 10993-1).

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