

HOVON

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AML MOLECULAR DIAGNOSTICS

Instructions: Please send the completed form to: HOVON Data Center, Erasmus MC - Daniel den Hoed, P.O. Box 5201, 3008 AE ROTTERDAM
 Use this form to report results of analysis of primary diagnosis and follow-up samples.
Use one line per performed test, fill out ALL items for each line..

Patient namecode: Hospital: Patient study number: | | | |

PATIENT DATA

HOVON protocol number | | | | (e.g. 42, 43, 81, 92, 102, 103,...)
 Date of birth [dd/mm/yyyy] | | | | | | | |
 Hospital record number
 Local lab for molecular diagnostics
 Molecular diagnostics done ? | | 0=no, 1=yes **Fill out and send in form also if not done!**

MOLECULAR ANALYSIS

Date of sample [dd/mm/yyyy]	Material 1=BM 2=PB	Technique 1=non-quant. PCR 2=quant. PCR 3=Southern Blot	Abnormality ^a , specify (if applicable)	Sensi- tivity ^b	Result 0= not detectable 1= detectable 9= not assessable
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^aAbnormality: 1= AML1/ETO t(8;21) 12 =NPM1 mut.
 2= CBFβ/MYH11 inv(16) 13= CEBPA mut.
 3= PML/RAR t(15;17) 14= EVI1 expr.
 4= DEK/CAN t(6;9) 15= KIT mut.
 5= 11q23 (incl. MLL-AF4 t(4;11)) ** 16= WT1 mut.
 6= BCR/ABL t(9;22) 17= MGMT expr.
 7= FLT3 ITD
 8= FLT3 D835
 9= IgH-BCL2
 10=IgH-CCND1
 11= Ig/TCR V-(D)-J 88= other** ** Specify in column Abnormality

^bSensitivity: 1=1/10¹ 2=1/10² 3=1/10³ 4=1/10⁴ 5=1/10⁵ 9=not assessable

Date: | | | | | | | | Name: Signature:

INSTRUCTIONS FOR FILLING OUT THE FORM

- 1 Fill out the HOVON protocol number on the form.
- 2 Fill out all 'Patient data'.
- 3 Per sample multiple tests/assays may have been done on BM and/or PB. Fill out the result of each test on a separate line, also if the result was negative or not assessable.
- 4 Fill out **all** items (from 'date' to 'sensitivity' plus the applicable 'result') for **each** line, even if they are the same as on the previous line. If you wish to indicate that a value (e.g. date or material) is the same for several consecutive lines, please use a clear marker to indicate this (like " ").
- 5 *Fill out Result with 0 = not detectable (previously labeled negative), 1= detectable (previously labeled positive), 9=not assessable*
- 6 Specification is required for abnormalities 5=11q23 and 88=other.
- 7 Specification is optional for the other abnormalities. It is intended for a specification of the breakpoint, e.g. p190 or p210 for BCR/ABL, or for the specification of the assay for the abnormality indicated by the code, e.g. MLL-AF4 or MLL-AF9 in case of an 11q23 abnormality.
- 8 Specifications should be entered on the dots behind the label box in the column 'abnormality'.

COMMENTS

- 1 Molecular Diagnostic (MD) information on patients in HOVON studies for which molecular diagnostics is relevant is collected through a special MD-form. The MD-form is not study-specific and the HOVON protocol number needs to be filled out on the form (42 for HOVON42 AML, etc.).
- 2 The HDC prefers to receive the MD information in electronic form directly from the MD Labs.
- 3 Otherwise the data have to be filled out on this MD form and sent in by the responsible local datamanager.
- 4 Since the molecular data require special knowledge for interpretation it is important that the forms are filled out by or in close collaboration with the Molecular Diagnostics coordinator who is responsible for molecular diagnostics in the hospital, or – if such a function does not exist – by the local investigator.
- 5 Use only the most recent Molecular Diagnostics form. Local Datamanagers will be notified of any updates of this form.
- 6 Incompletely filled out forms cause problems with data entry by a data typist and will be sent back for proper completion.
- 7 In most cases molecular diagnostics will be performed at diagnosis and at several timepoints during follow up. The assays are usually done in a specialised laboratory. The results of analysis at primary diagnosis will generally be available within one month after registration of a patient in a study. This information should be sent in together with the on study and treatment forms.
- 8 Follow up material of patients with a molecular abnormality at diagnosis will generally be stored and processed in batches at a later time. Moreover, as new markers become available, additional analyses may be done at a later time on stored material. The local data manager should check for the availability of new MD results for patients with a molecular abnormality at diagnosis when filling out treatment evaluation CRF's or follow up CRF's, or at the request of HOVON Data Center. The updated MD-form can then be sent together with the usual CRF's to the HOVON Data Center.

SENDING OF FORMS

- 1 All forms have to be sent to:
HOVON Data Center, Erasmus MC – Daniel den Hoed, P.O. Box 5201, 3008 AE ROTTERDAM, The Netherlands.
- 2 Send in the original CRF's, completed, dated, named and signed by the responsible Molecular Diagnostics local coordinator, the local investigator or the person who has been authorised by the investigator to be responsible for the quality of the data on his/her behalf.
- 3 Keep a copy of all CRF's.
- 4 Corrections and additions afterwards can be made as follows:
On top of your copy of the CRF's write "revised" or "updated". Write the corrections/additions on this copy and initialize and date the form. Make a copy for your own files and send the revised CRF pages to the HDC.