

2013 BHS Meeting Molecular Hematology: overview on activity



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25 January 2013



History

- | Royal Decree 1998: Centres for Molecular Diagnostics (CMDs)
- | 2000: from 10 to 18 CMDs
- | CMDs
 - g Transient solution
 - g Fixed RIZIV/INAMI budget (6,5 Mio €)
 - g Finances: fixed and variable budget/centre
- | 2005: legal basis rejected by Council of State
- | 01/08/2007: art 33 bis nomenclature!

Molecular Hematology

- | Each center needed BELAC accreditation for reimbursement
- | Actually 16 centres accredited for Art33bis (Flanders =8, Brussels= 3, Walloon =5).
- | Meanwhile: 5 years nomenclature...
- | Time to look at the evolution of the number of tests performed
- | Data available in Econodat (Besco) from 1/8/2007 till 2011
- | Analysis period: 2008-2011

Molecular Hematology

- | No data on individual centres
- | reimbursement not into Clinical Biology
“forfait”regulation. Invoice to Social security, not to patients.
- | No “subcontractance” regulation
- | Reimbursement/test: unchanged, only index increase (B3000: 115€->123€)
- | JAK-2: reimbursed since 01/08/2010. No data available.

Molecular Hematology

- | Hematology: 6 diagnostic numbers, 2 follow-up numbers
- | Oncology: 3 diagnostic, 1 follow-up
- | Others: 3 (factor 5, Factor 2, fetal Resus)

Detection of Translocation in Acute leukemia, RAEB (558431-588442)



- | Corresponds to Hemavision testing (28 translocations or selected panel, FLT3, NPM1, CEBPa,..)
- | Max. 5/each diagnostic fase; IgH and TCR testing are excluded

Detection of Translocation in Chronic Lymphoid disease, 588453-588464

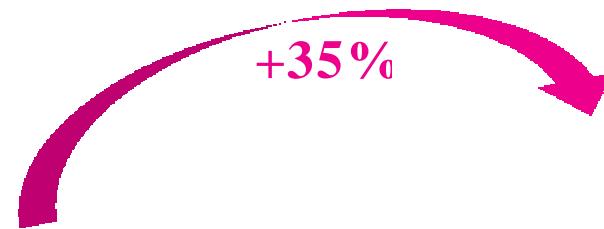


| NHL, CLL, MM,

Max. 3/each diagnostic fase, IgH and TCR testing are excluded

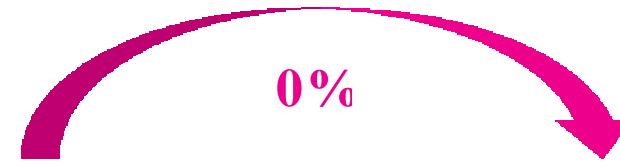


Detection of Ig/TCR rearrangement in CLL or NHL, 588475-588486



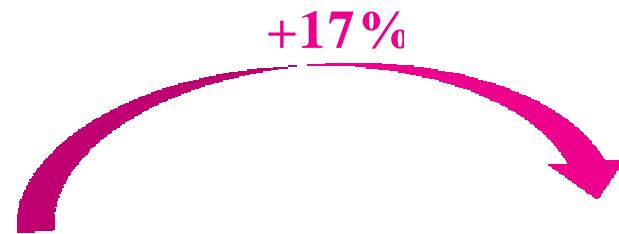
| Max. 2/each diagnostic fase/for each tissue

Detection of Ig/TCR rearrangement in ALL(1), 588490-588501



- | (1) Burkitt's lymphoma or T/B lymphoblastic lymphoma
- | Max. 2/each diagnostic fase/for each tissue

Detection of BCR/ABL translocation in CML, 588512-588523



- | Max. 1/each diagnostic fase.

Follow-up of BCR/ABL

588593-588604



- | Real-Time PCR
- | Max: 4/year; 900 patients in FU

Follow-up of lymphoid or myeloid disease, 588571-588582



| Max. 1, 4x/year

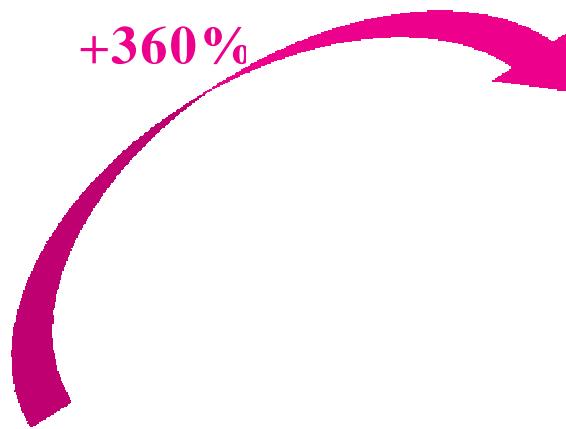
Chimerism testing

- | Blue bars: patient pre-Tx, orange bars: donors, green bars: patient post-Tx.
- | Max. 6/first year; max. 4/next 4 years.
- | Increase: **52%**
- | Nomenclature not for T-cel chimerism!

Contamination of malignant cells in cell preparation, 588836-588840

- | Max. 1/apheresisprocedure (not collection!)
- | Not done, forgotten or other number used?

Detection of gene/chromosome abnormality in solid tumor, 588534-588545



- | Max. 2 in each diagnostic fase (B3000)
- | EGFR, B-RAF, MDM2, ...accreditation dependent.

Detection of HER2/NEU oncogene, 588556-588560



- | Max. 1 in each diagnostic fase (B8000)

Molecular Hematology:

Total number of tests (1)



- | (1) without JAK-2, factor 2 and 5, fetal resus !

Molecular Hematology + Oncology:

Total number of tests (1)



- | (1) without JAK-2, factor 2 and 5, fetal resus, K-RAS, FU of solid tumor.

New proposals Art 33bis

- | A number of proposals are submitted to the Commission of Clinical Biology for introduction into Art 33bis:
- | Introduction of T-cell chimerism
- | Introduction of a number for chronic myeloproliferative disease, max. 2 (includes BCR/ABL and Jak-2; JAK-2 on itself would be scratched).
- | CGH microarray for CLL and MM
- | VH-Hypermutation status in CLL
- | Others.....

Molecular Hematology

- | Budget Art33bis:
- | estimated $3,3 \cdot 10^6$ €/year(100%)

- | 2008: $3,9 \cdot 10^6$ € (118%)
- | 2009: $4,6 \cdot 10^6$ € (139%)
- | 2010: $6,6 \cdot 10^6$ € (200%)
- | 2011: $7,7 \cdot 10^6$ € (233%)
($310 \cdot 10^6$ BF)

Molecular Hematology

- | Number of tests presented are probably underestimated (counting from previous year closes July following year = tests performed in 2011 invoiced after july 2012 not counted, but reimbursed).
- | Future? Increase of expenses will maybe stimulate Clinical Biology “forfait” regulation!
- | Increase already questioned in the senate 2012

THE END...for the moment.

