# “Different roads sometimes lead to the same castle”: a survey on the profile and functions of medical molecular biologists in Belgian clinical labs

# FINAL REPORT

Survey organized by MolecularDiagnostics.be
from 28/04/2015 to 01/06/2015

# COLOPHON

**Title:**
"Different roads sometimes lead to the same castle": a survey on the profile and functions of medical molecular biologists in Belgian clinical labs

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**Disclaimer:**
The views and opinions expressed in this report are those of the authors and not necessarily those of the individual respondents.

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**Quote in title**:
G.R.R. Martin, *A Game of Thrones*.

## INTRODUCTION

In many countries, the practice of specific medical and paramedical professions is regulated by law. The necessity to obtain an official recognition ensures the professional that they do not have to compete with individuals lacking the required education. More importantly, it ensures treatment of patients and analysis of patient samples by dedicated and skilled personnel. To be allowed to work in Belgian clinical labs, clinical biologists, pathologists, medical geneticists and, since recently, medical laboratory technicians (MLTs) need an official recognition, provided by the federal government. During the last two decades, larger clinical and pathology laboratories recruited specialists, a very broad group which can be referred to as “biomedical scientist-specialists”. As currently an official title is lacking, these people are often referred to as “scientific collaborator”. They were recruited on the basis of their profound experience and (technical) knowledge in different fields, such as embryology, toxicology, or molecular biology. Especially the involvement of the latter group is steadily growing in all disciplines of clinical laboratories. We refer in this case to ‘medical molecular biologists (MMBs)’.

In contrast to the Netherlands (Dubbink et al., 2014), there is no specific education for the function of MMB in Belgium and as a result, this job is performed by skilled personnel with a broad variety in academic degrees and professional experience. On a European level, initiatives from the “European Skills, Competences, Qualifications and Occupations” (ESCO; https://ec.europa.eu/esco) and the “European Society for Professions in Biomedical Science” (EPBS; www.epbs.net) are pursuing pan-European harmonization of the education and professional recognition of the different types of scientists in biomedical labs.

As outlined below, highly skilled MMBs are performing specialized tasks which are different from the tasks that MLTs are trained to do. In the context of the official recognition of MLTs in Belgium, MMBs would no longer be permitted to perform their job. As a temporary solution, the majority of MMBs have applied for the title of MLT to be able to continue their work legally. As a result, the Federal Public Service Health, Food Chain Safety and Environment (http://www.health.belgium.be/eportal) now has a large number of applications from highly educated professionals who do not qualify as MLT. Importantly, these MMBs are not seeking official recognition as MLT but clearly need to obtain an official recognition to be able to continue their work legally. MolecularDiagnostics.be (www.moleculardiagnostics.be) is the only professional society representing MMBs working in Belgian hospital labs and one of our goals is to represent our members to official agencies.

A survey querying the profile and tasks of MMBs was performed among the members of MolecularDiagnostics.be. The results were analyzed anonymously and a list of the participants is added as Addendum 1 to this report. In total, the 39 participants represent 17 different Belgian hospitals and more than 400 years of experience of working as an MMB in a clinical lab. We believe this survey therefore brings a representative picture of the profile and functions of MMBs in Belgian clinical laboratories.

# RESULTS

## SECTION I: PROFILE

In the first part of the survey, we investigated the profile of MMBs. All respondents are active in labs affiliated to a hospital, with 41% affiliated to a university hospital.

A wide variety in educational degrees is found in the group of participants. About two thirds has a PhD degree while the other third has a master's degree (Figure 1). Numerous different titles on the degree (e.g. biotechnology, biomedical sciences, biochemistry,…) is a sign that people with different academic backgrounds are well-educated for this job. In total, 12 different titles were reported (5 PhD, 1 Manama, 5 Master and 1 bachelor).

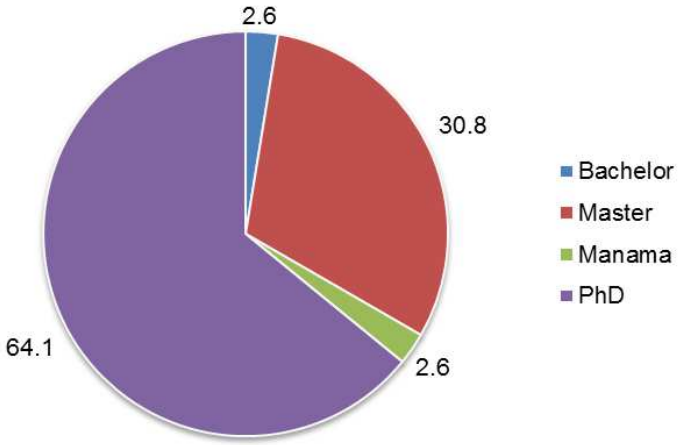


**Figure 1. Distribution of academic degrees for MMBs working in clinical labs (%).**

People working as an MMB are generally employed with a contract of unlimited duration (91.9 %), of which 17.9 % are statutory contracts (Figure 2). Only a minority has a contract with limited duration. Two thirds of the MMBs work full time and the majority (77%) of the part-time workers works 80%.

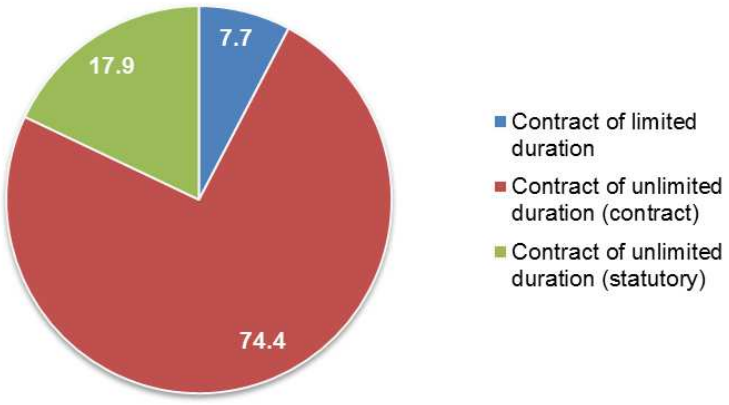


**Figure 2. Distribution of contract types for MMBs (%).**

MMBs are active in different disciplines and/or different hospital departments. The most common disciplines are: pathology (acquired genetic changes in solid tumors), hematology (acquired genetic changes in hematological malignancies), genetics (hereditary genetic abnormalities) and microbiology (detection of pathogens, i.e. viruses, bacteria or parasites). In most hospitals, different departments are responsible for the molecular tests in the four disciplines. The departments work independently and each has its MMB(s). Other hospitals combine the different disciplines in one molecular laboratory platform and require a broader expertise of their staff. The respondents of the survey are mostly active in microbiology (Figure 3) but show a good overall distribution over the disciplines and perform, on average, tasks for 1.6 disciplines. A majority (51.3 %) is only involved in one discipline, but 35.9 % work in two disciplines, and only 12.8 % are active in 3 disciplines.

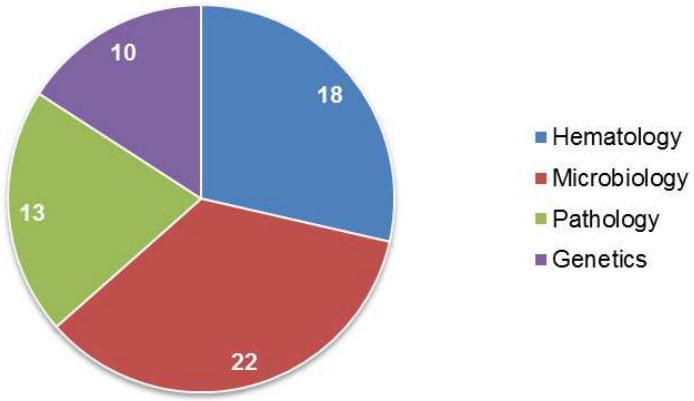


**Figure 3. Number of respondents active in the different disciplines.**

Most MMBs do not perform the practical handling involved in routine testing (see below), but have to instruct MLTs. The number of MLTs supervised is quite diverse (Figure 4, range from 0 to 28) and on average, an MMB supervises 5.1 MLTs. Overall, supervision of MLTs is a common responsibility of MMBs as 95 % perform supervision of at least one MLT.

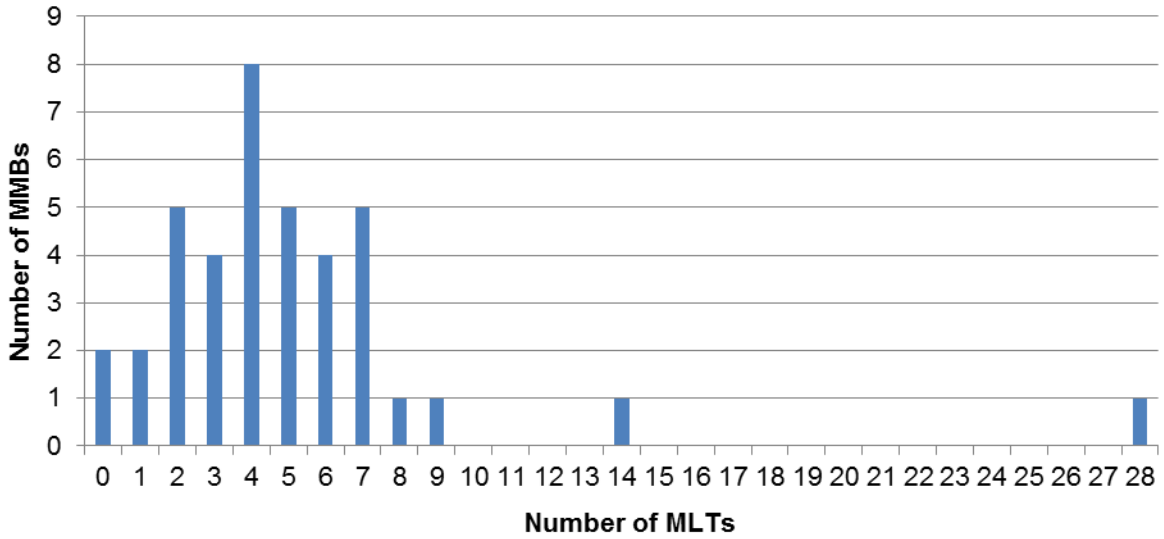


**Figure 4. Overview of the number of MLTs supervised by the number of MMBs.**

## SECTION II: FUNCTIONS

A) GENERAL

We strongly believe that MMBs have a different function in molecular clinical labs as compared to MLTs. To investigate this, we first queried the practical work. Only a minority of MMBs (10.3%) is never found at the bench while a big majority (84.6 %) does practical work at least in the context of validating a new test. When implementing a new test in the laboratory, it is valuable to go through all the steps of the process in order to setup and maintain the quality system and to perform adequate troubleshooting. About half of the MMBs perform routine testing on busy moments (41.0 %) or act as a back-up when, for instance, an MLT falls ill (59.0%). Only a small minority is taken up in a schedule to perform practical tests on a routine basis (7.7%). Apart from the simple routine tests, one third of the MMBs (33.3%) perform tests for which specific expertise is required. For instance for the analysis of sequencing profiles, HIV genotyping or FISH interpretation.

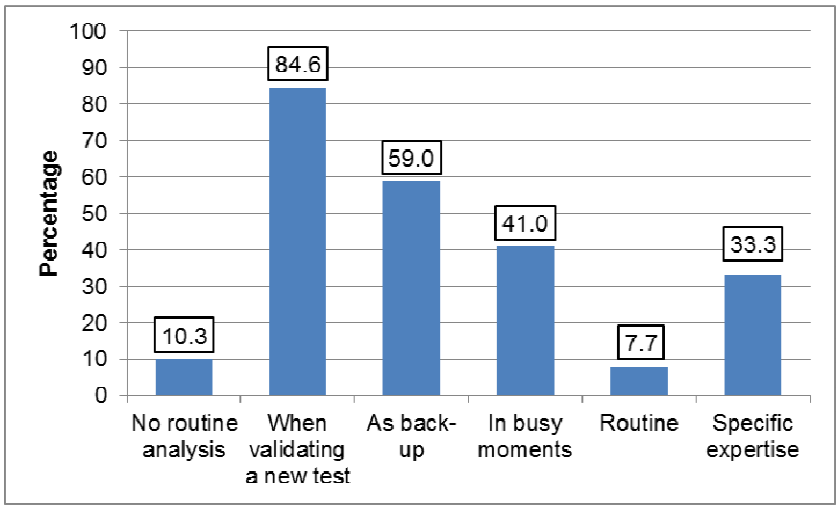


**Figure 5. Percentage of MMBs performing routine analysis in specific set-ups.**

From the data presented above, it is clear that MMBs have, to a minor extent, overlapping functions to MLTs. However, for most MMBs, the majority of their time is dedicated to specific tasks which are normally not performed by MLTs (see below).

Next, we queried the time spent by MMBs in three sectors: research, academic education and routine diagnostics. Time spent on the three categories is quite diverse (Table 1 and Figure 6). Although all respondents are active in **diagnostics**, this ranges from 10 to 100 % of their time. However, a majority of participants spends most of their time on diagnostics (median = 85 %). The time spent on **research** is even more variable and ranges from 0 (n=3) to 80 %. In general, research is only a side-activity for most people. **Academic education** is found to be least time-consuming, with 43.6 % of people spending less than 5% of their time.

**Table 1. Summary of time distribution of MMBs (percentages).**

| | Research | Academic Education | Diagnostics |
|---|---|---|---|
| **Median** | 10 | 5 | 85 |
| **Average** | 18.1 | 4.3 | 77.0 |
| **Standard Deviation** | 20.7 | 4.4 | 23.3 |
| **Relative standard deviation** | 114.3 | 104.5 | 30.3 |
| **Minimum value** | 0 | 0 | 10 |
| **Maximum value** | 80 | 20 | 100 |

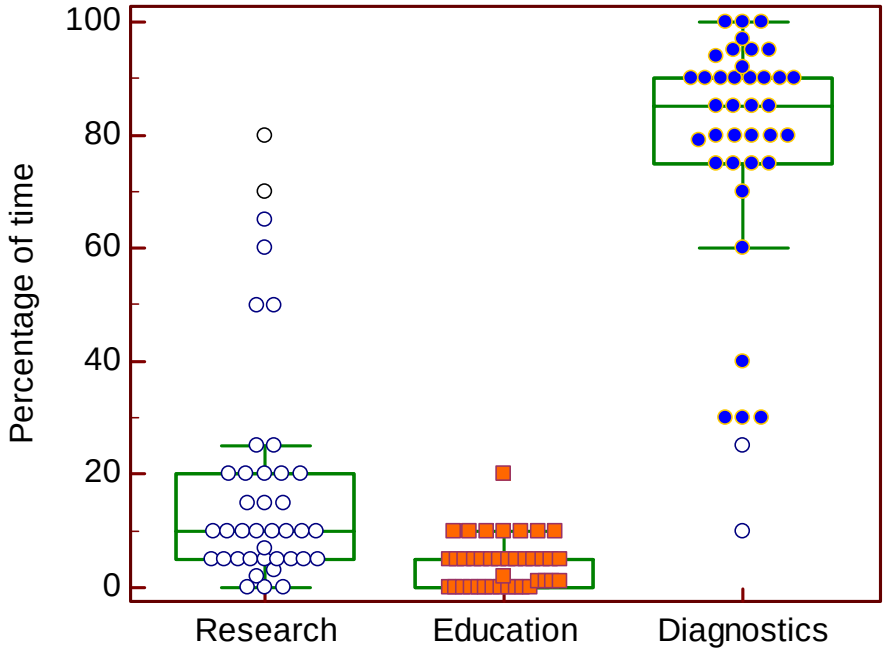


**Figure 6. Box-plot of time distribution of MMBs.**

To narrow down the different tasks of an MMB, we further subdivided the three sectors in separate tasks and responsibilities and asked participants to score each task on how frequently they do this (daily, regularly, sporadically, never). Below, we highlight some interesting results. The full table with all the questions and percentages is available as Addendum 2.

## B) RESEARCH

Even though the total amount of time spent on research is quite low on average, almost one fifth of respondents (17.9%) is daily involved in research and almost half does so on a regular basis (48.7%). For most respondents, this results in scientific articles and presentations on scientific meetings although over 10 % never spends time on presenting results to the scientific community.

## C) ACADEMIC EDUCATION

Providing academic education to undergraduate students is a minor activity for most MMBs. Even though half of the respondents is connected to a university hospital, this does not translate further in teaching responsibilities as 64.1 % never teaches nor supervises practical exercises. MMBs do however have a link to the academic world as 51.3% of the respondents indicated that they function as experts in examination committees.

On the contrary, the practical, on-the-job, training of undergraduate students is a frequent activity for a lot of MMBs (59.0 % for bachelor students and 35.9 % for master students).

## D) DIAGNOSTICS

Working as an MMB in a clinical molecular lab involves the supervision of technicians performing the practical work. As such, some MMBs have specific management functions. For instance, the planning of working hours for the personnel is a daily occupation for 10.3 %, while another 53.8 % is involved on a regular to sporadic basis. One third (35.9 %) of MMBs never spends time on these issues. Similar results were obtained on maintaining personnel records, personnel appraisal or responding to questions of personnel administration. Even though 95 % of MMBs supervise at least one MLT, it is striking that almost half (41.0 %) never had any management training and that more than half (51.3 %) do not conduct performance appraisal of the people they supervise. Either this is because this is not mandatory or because it is performed by somebody else.

The practical planning of the lab is a common responsibility for MMBs, as 17.9 % does this on a daily basis and another 35.9 % on a regular basis. In contrast, about one quarter is never involved in this, highlighting specific differences between either different institutions or different levels of MMBs. Similarly, a vast majority organizes work meetings (82.1 %) on a regular basis while only a minority (10.3 %) never does.

The practical training of MLTs is a frequent activity for most MMBs and this is supplemented by theoretical training, which is done both in-house (92.3 % do this on a regular or sporadic basis) or external (66.6 %). The own continuing education is guaranteed by a regular (64.1 %) or sporadic (35.9 %) attendance at scientific meetings. Although there is currently no obligation to attend meetings, in contrast to other (para)medical professionals, all respondents in the survey do this at least on a sporadic basis.

As mentioned above, some MMBs perform routine analyses, identical to the work performed by MLTs, but most do this only in special circumstances. For more than half (53.8 %) this occurs on a sporadic basis. However, there is a small minority (5.1 %) that does so on a daily basis, making the difference between an MMB and an MLT faint for these few individuals. Importantly, more than one quarter (28.2 %) never performs simple routine tests. Illustrating the different responsibilities, more MMBs perform complex routine analysis (38.5 %) than simple routine analysis (17.9 %), on a regular basis.

The most important task of most MMBs is the technical supervision and validation of the routine analyses performed by the MLTs. For instance, 94.9 % does this on a daily to regular basis, and none are never involved. This is accompanied by the regular technical troubleshooting of the problems occurring in the lab (89.8 %). Another core task of most MMBs is the development and validation of novel assays, with over 80 % spending time on these on a regular basis.

We conclude that the profile of MMBs has **four core elements**: 1) the development of novel assays based on state-of-the-art knowledge, 2) the technical validation of routine analyses, 3) the overall technical supervision and troubleshooting of the lab, and 4) the maintenance of the high quality standards. Other activities are not so common for MMBs. For instance, service contracts are dealt with on a regular basis by more than 50 % of MMBs, while another 20 % never deals with these. A similar result is obtained for performing internal audits, where almost 80 % performs this with a regular to sporadic frequency, while the remaining 20 % is never involved. It is possible that these tasks are delegated to the MMBs if the laboratory organization is lacking support for this task by other personnel.

## CONCLUSIONS

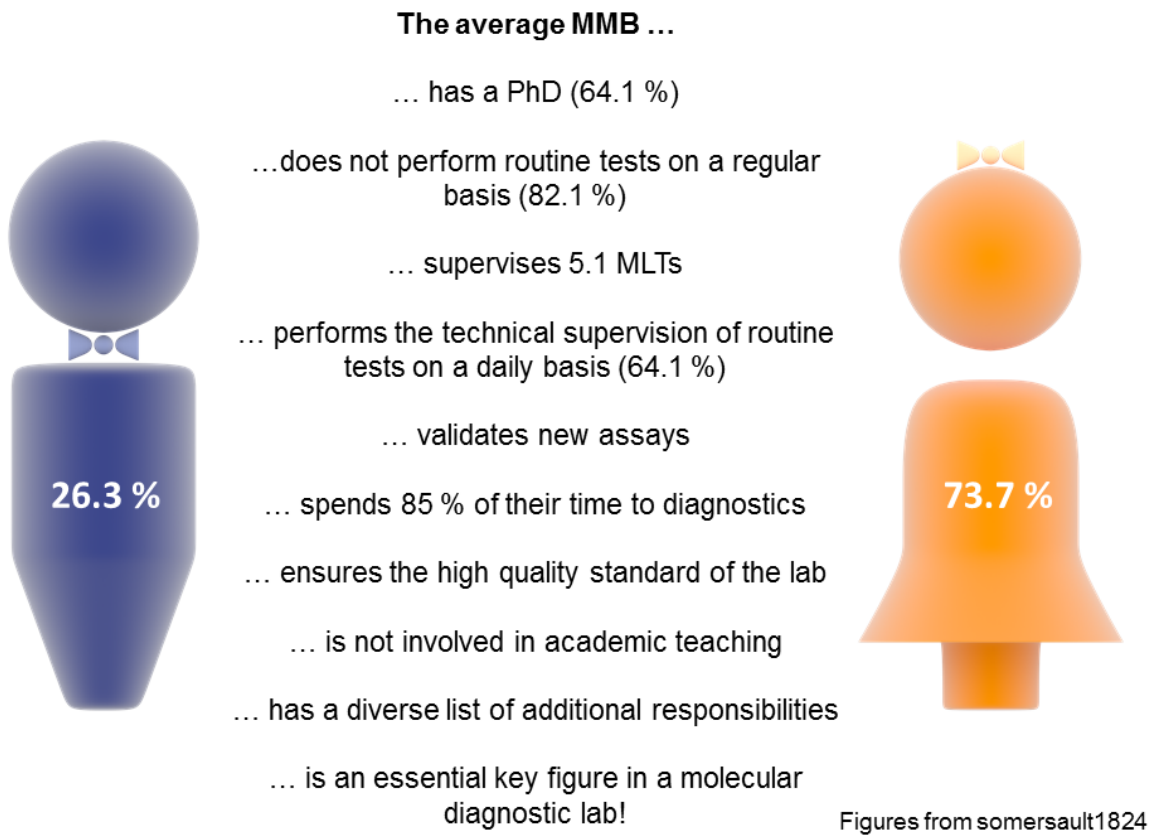


**Figure 7. The average MMB.**

## RECOMMENDATIONS

Most MMBs applied for the professional title of MLT to be legally allowed to continue working in a diagnostic lab and to handle patient material. They obtained a temporary visum which allows them to continue their job until December 1st, 2019, so this is only a temporary solution. As shown by the results of this survey, both the profile and functions of MMBs are quite distinct from those of MLTs. Consequently, we believe a system should be put in place that provides MMBs with a specific professional title. As expert scientists are also active in other disciplines of medicine (e.g. embryology), we believe the recognition of MMBs should be incorporated in a larger group of "**Biomedical Scientists-Specialists**".

The important role for MMBs in molecular diagnostic labs was also highlighted in a recent report from the KCE (Van Den Bulcke et al., 2015) on next-generation sequencing. There, the authors recommend the installation of multidisciplinary "molecular advisory boards" for the choice of targets, the implementation of the test and the interpretation of the detected variants. These boards include expert clinicians, pathologists or clinical biologists (depending on the tumor type), *scientists*, ethicists and bio-informaticians when applicable. It is clear that the "scientists" mentioned in this report are similar to MMBs described here, as several MMBs already function in these types of boards.

MolecularDiagnostics.be is willing to contribute to refine criteria and establish training programs for this specific professional title to ensure continued high quality molecular diagnostics in Belgium. Importantly, it is our opinion that professionals currently working as MMBs should receive official recognition as MMB, regardless of their academic degree, provided that they have at least two years of experience as MMB. Below, we provide a starting point in the discussion how new MMBs can obtain a professional recognition.

As specific academic training does not exist, we propose an on-the-job training period of two year to obtain recognition as an MMB. At the start, trainee-MMBs should have at least a Master degree in a biomedical field (e.g. master in biomedical sciences, biotechnology, biology, …), and already have a minimum of two years hands-on experience in a molecular biology laboratory, preferably in a biomedical setting. This experience can be either in an academic setting (e.g. during a PhD), in an industrial (biomedical) setting or in a clinical laboratory setting. Subsequently, a provisional visum allows the applicant to enter a period of on-the-job training of two year, under the official supervision of a recognized MMB. During this training period, a defined theoretical and practical training program should be followed. After successful evaluation, a recognition as MMB is obtained. The details on the requirements and evaluation of the training remain to be discussed with the appropriate authorities. Once the recognition is obtained, an official system of continuous education, similar to those established for other (para)medical professions, should be followed to maintain the high quality standards of the skilled professional.

## REFERENCE LIST

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Van den Bulcke M, San Miguel L, Salgado R, De Quecker E, De Schutter H, Waeytens A, Van Den Berghe P, Tejpar S, Van Houdt J, Van Laere S, Maes B, and Hulstaert F. 2015. **Next generation sequencing gene panels for targeted therapy in oncology and haemato-oncology**. Health Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). KCE Reports 240. D/2015/10.273/26.

# ADDENDA

## ADDENDUM 1: ALPHABETIC LIST OF PARTICIPANTS

| Name | First Name | Institution |
|---|---|---|
| Bakkus | Marleen | UZ Brussel |
| Bergs | Kristof | UZ Antwerpen |
| Beuselinck | Kurt | UZ Leuven |
| Boone | Elke | AZ Delta Roeselare |
| Breyne | Joke | AZ Delta Roeselare |
| Caberg | Jean-Hubert | CHU Liège |
| Castermans | Emilie | CHU Liège |
| Cnops | Lieselotte | ITG Antwerpen |
| De Kelver | Wim | UZ Leuven |
| De Rauw | Klara | UZ Brussel |
| Demartin | Sonia | Jolimont La Louvière |
| Deplano | Ariane | ULB Erasme Bruxelles |
| Descheemaeker | Patrick | AZ Sint-Jan Brugge |
| Detemmerman | Liselot | UZ Brussel |
| Dewaele | Barbara | UZ Leuven |
| Echahidi | Fedoua | UZ Brussel |
| Franke | Sabine | CHU Liège |
| Hillen | Femke | Jessa Ziekenhuis Hasselt |
| Koopmansch | Benjamin | CHU Liège |
| Lambin | Suzan | UZ Antwerpen |
| Micalessi | Isabel | Imelda ziekenhuis Bonheiden |
| Nollet | Friedel | AZ Sint-Jan Brugge |
| Raymaekers | Marijke | Jessa Ziekenhuis Hasselt |
| Soetens | Oriane | UZ Brussel |
| Ursi | Dominique | UZ Antwerpen |
| Vaeyens | Freya | OLVZ Aalst |
| Van Lint | Philippe | GasthuisZusters Antwerpen |
| Vancutsem | Ellen | UZ Brussel |
| Vandebroek | Katrien | Ziekenhuis Oost-Limburg Genk |
| Vandepoele | Karl | UZ Gent |
| Vander Borght | Sara | UZ Leuven |
| Vankeerberghen | Anne | OLVZ Aalst |

| | | |
|---|---|---|
| Vanlaere | Elke | AZ Sint-Lucas Gent |
| Vanmassenhove | Ben | AZ Damiaan Oostende |
| Vermeulen | Katrien | UZ Antwerpen |
| Vranckx | Hilde | UZ Leuven |
| Wautier | Magali | WIV Brussel |
| Zwaenepoel | Karen | UZ Antwerpen |
| Anonymous | Anonymous | Unknown |

## ADDENDUM 2: LIST OF TASKS

Full list of tasks/responsibilities (highest scoring group shown in green)

| | Daily | Regularly | Sporadically | Never |
|---|---|---|---|---|
| Set up research strategy and perform research | 17.9 | 48.7 | 33.3 | 0.0 |
| Publish scientific articles | 0.0 | 17.9 | 69.2 | 12.8 |
| Present (oral/poster) on a scientific meeting | 0.0 | 33.3 | 53.8 | 12.8 |
| | | | | |
| Teach courses (college or university) | 0.0 | 5.1 | 30.8 | 64.1 |
| Supervise practical exercises | 0.0 | 7.7 | 28.2 | 64.1 |
| Act as a jury member in examination committee | 0.0 | 10.3 | 41.0 | 48.7 |
| | | | | |
| Budget management | 5.1 | 30.8 | 38.5 | 25.6 |
| Personnel planning (time registration) | 10.3 | 33.3 | 20.5 | 35.9 |
| Manage personnel records and education | 5.1 | 48.7 | 15.4 | 30.8 |
| Perform performance appraisal | 2.6 | 25.6 | 20.5 | 51.3 |
| Reply to questions regarding personnel administration (e.g. change of working time, holiday regulations, …) | 2.6 | 10.3 | 30.8 | 56.4 |
| Follow management courses | 0.0 | 15.4 | 43.6 | 41.0 |
| | | | | |
| Training MLTs (practical) | 7.7 | 53.8 | 35.9 | 2.6 |
| Supervising undergraduate MLT (or other bachelor level students) | 2.6 | 56.4 | 35.9 | 5.1 |
| Supervising undergraduate master students | 2.6 | 33.3 | 43.6 | 20.5 |
| Train students in clinical biology | 0.0 | 30.8 | 33.3 | 35.9 |

| | Daily | Regularly | Sporadically | Never |
|---|---|---|---|---|
| Give internal lectures | 0.0 | 48.7 | 43.6 | 7.7 |
| Give exteral lectures (e.g. workshop) | 0.0 | 12.8 | 53.8 | 33.3 |
| Participate in molecular biology conferences | 2.6 | 61.5 | 35.9 | 0.0 |
| Make a work planning for the lab | 17.9 | 35.9 | 23.1 | 23.1 |
| Organize work meetings | 2.6 | 79.5 | 7.7 | 10.3 |
| Pick-up samples, make work lists | 12.8 | 28.2 | 48.7 | 10.3 |
| Perform simple routine analyses | 5.1 | 12.8 | 53.8 | 28.2 |
| Perform complex routine analyses for which specific expertise is required | 2.6 | 35.9 | 46.2 | 15.4 |
| Perform and validate internal quality controls | 20.5 | 56.4 | 17.9 | 5.1 |
| Perform technical validation of tests | 64.1 | 30.8 | 5.1 | 0.0 |
| Enter results into the LIS and check input | 53.8 | 38.5 | 7.7 | 0.0 |
| Store records/overviews | 38.5 | 56.4 | 5.1 | 0.0 |
| Solve technical problems | 43.6 | 46.2 | 10.3 | 0.0 |
| Approve/submit supply orders | 17.9 | 56.4 | 20.5 | 5.1 |
| Study literature | 25.6 | 59.0 | 15.4 | 0.0 |
| Develop new assays | 17.9 | 61.5 | 20.5 | 0.0 |
| Perform risk analyses | 2.6 | 41.0 | 48.7 | 7.7 |
| Implement new equipment | 5.1 | 53.8 | 41.0 | 0.0 |
| Optimization of existing procedures | 15.4 | 79.5 | 5.1 | 0.0 |
| Validation of procedures | 10.3 | 79.5 | 7.7 | 2.6 |
| Write validation files | 7.7 | 87.2 | 5.1 | 0.0 |
| Perform validation of software (updates) | 5.1 | 64.1 | 30.8 | 0.0 |
| Write SOPs | 7.7 | 76.9 | 15.4 | 0.0 |
| Analyze anomalies | 30.8 | 51.3 | 7.7 | 10.3 |
| Systematic analysis of anomalies | 5.1 | 64.1 | 20.5 | 10.3 |

| | Daily | Regularly | Sporadically | Never |
|---|---|---|---|---|
| Manage external quality evaluations | 7.7 | 71.8 | 20.5 | 0.0 |
| Manage maintenance and repair of equipment | 5.1 | 59.0 | 28.2 | 7.7 |
| Manage maintenance contracts | 2.6 | 48.7 | 28.2 | 20.5 |
| Manage pipette calibration | 0.0 | 30.8 | 33.3 | 35.9 |
| Manage product sheets, manuals, MSDS, COA, … | 2.6 | 46.2 | 28.2 | 23.1 |
| Perform internal audits | 0.0 | 38.5 | 41.0 | 20.5 |
| Write action plan following internal or external audit | 2.6 | 59.0 | 25.6 | 12.8 |
| Central contact in internal/external audit | 5.1 | 56.4 | 23.1 | 15.4 |
| Manage lab safety | 2.6 | 28.2 | 46.2 | 23.1 |
| Write reports (e.g. annual account) | 0.0 | 56.4 | 38.5 | 5.1 |
| Have contacts with companies to stay up-to-date with recent developments | 2.6 | 74.4 | 23.1 | 0.0 |
| Negotiate with suppliers on reagent contracts | 0.0 | 64.1 | 23.1 | 12.8 |
| Advisory role in the purchase of reagents and equipment | 2.6 | 71.8 | 23.1 | 2.6 |
| Discuss changes in the LIS with the LIS responsible | 2.6 | 59.0 | 33.3 | 5.1 |
| Keep lab guide up to date | 2.6 | 51.3 | 30.8 | 15.4 |
| Collaborate on clinical trials | 5.1 | 33.3 | 48.7 | 12.8 |
| Advisory role in projects of other departments of the lab | 0.0 | 25.6 | 56.4 | 17.9 |