UBIT COLLEGE
(University for Business and Technology)

Laborant of Biochemical Medicine/BSc

RECCRREDITATION

May 21, 2019, Pristina

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1. INTRODUCTION

1.1. Context

Date of site visit: May 31, 2019

Expert Team (ET) members:

A. Prof. Dr. Milan Pol

B. Prof. Dr. Alan Brickwood

C. Prof. Dr. Peter Parycek

D. Prof. Dr. Zdravko Lackovic

E. Prof. Dr. Ulrike Beier

F. Student Expert TBC

Coordinators from Kosovo Accreditation Agency (KAA):

- Avni Gashi, Acting Director of KAA
- Shkelzen Gerxhaliu, Senior Officer for Evaluation and Monitoring
- Arianit Krasniqi, Senior Officer for Evaluation and Accreditation

Sources of information for the Report:

A. A Self-Evaluation Report (SER) submitted by UBIT

B. Information obtained during the site visit;

C. Meetings conducted with the management of the institution, teaching and administrative staff, students, graduates, external stakeholders and employers of graduates;

Criteria used for program evaluation:

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1.2. Site visit schedule

31 May

09.00 – 10.30 Meeting with the management of the institution

10.40 – 11.50 Meeting with quality assurance representatives and administrative services

12.00 – 13.00 Meeting with the heads of study programs

13.00 – 13.50 Lunch break

13.50 – 14.50 Visiting tour of the facilities and infrastructure

14.50 – 15.40 Meeting with teaching staff

15.50 – 16.40 Meeting with students

16.50 – 17.40 Meeting with graduates

17.50 – 18.40 Meeting with employers of graduates and external stakeholders

18.45 – 19.00 Internal meeting – Expert Team and KAA

19.00 – 19.15 Closing meeting with the management of the institution

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1.3. A brief overview of the institution and program under evaluation

University for Business and Technology (UBT) is a private university located in Kosovo. The College was licensed to operate as a private bearer of higher education by the Ministry of Education, Science and technology no. 808/02-1, date. 18.10.2004. UBT student orientation is balanced between three broad areas: (1) ICT, mathematics and natural science, (2) Engineering, manufacturing and construction and (3) social science.

UBT operates in several locations and branches, and its infrastructure houses one the largest libraries in Kosovo and over 80 laboratories. It has offices and contact points in all regions of Kosovo and abroad (UBT Prishtina Campus, UBT Innovation Campus, UBT Prizren Campus, UBT Ferizaj Campus, UBT Peja Campus – Dukagjini College, UBT Gjilan Campus – Arberi College, UBT Austria Office, UBT Hungary Office)

Summarized general information about the institution and the Laboratory Medicine program under evaluation,

Name of the institution	BPRAL UBT College
Faculty/Department	Department of Life Sciences
Main Campus or Branch	Main Campus
The program applies to Branch	No
Name of the study program	Biomedical Laboratory Technician
Person responsible	Linda Carkaxhiu
Accreditation/Reaccreditation	Accreditation
NQF Qualification Level	NQF Level 6
Academic degree conferred	Laboratory Technician
ECTS	180
Program profile (specialization)	Health Care
Erasmus Code	
Type of study	Full-time
Number of students	150
Minimum duration of study	3 years

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2. PROGRAM EVALUATION

2.1. Mission, objectives and administration

Higher Education at PBHE The UBT College is developed in compliance with the principles and standards of the European Higher Education Framework (EHEF), reflecting the principles and objectives of the Bologna Process (UBT Statute Article 4)

According to *UBT Statute:*
The mission of the BPrAL College UBT is:
a) To create, convey, develop and generate knowledge through teaching, research, aiming to prepare qualified specialists and future scientists;
b) Provide opportunities to benefit from lifelong higher education;
c) To assist economic development at national and regional level;
d) Contribute to the enhancement of the standards of democracy and civilization of society and in the preparation of young people for such a society;
e) Realizes basic and applied research by means of organizational, core and subsidiary units;
f) Provides service to third parties, in compliance with the mission and legal status.

The UBT curriculum generally adheres to the EC Directive and meets the minimum theoretical/practical ratio defined therein.

The Directive is vague in terms of the number of hours dedicated to theoretical instruction and practice. However, the institution has attempted to follow the Bologna and Munich Declarations on health care education and enshrined the good practices recommended by the World Federation of Medical Education and consulted a number of curricula in EU counties

The medical laboratory technician, as a member of the health-care team, performs laboratory investigations related to the diagnosis, treatment and prevention of disease, including analysis of a variety of specimens such as blood, urine, faeces, sputum and tissues. Technologists also have significant patient contact primarily through blood collection.

Students have the opportunity to first practice, and then become capable of a variety of competencies. They prove competence during real-life experiences in a clinical setting. As the activities are in the most part of practical nature, the study program is designed to have 50% of curricula with practical contents, i.e. demonstration classes and clinical practice. Site visits and practice placements are important features of the teaching and learning process.

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Opportunities for interactive learning are reinforced through project-based learning, case study analysis, visiting speakers, group work and e-learning.
The volume of studies of Medical Laboratory is 300 ECTS (p. 347) learned through theoretical and practical classes, independent work and practical exercise at medical institutions and the activities are accomplished during the 5-year programme (10 semesters). (In ECTS, 60 credits represent the workload of a year of study; normally 30 credits are given for a semester. One ECTS credit is equivalent to 30 hours of students' workload.) Teaching is organised at the Faculty, UBT Medical Laboratory Clinic and medical institutions contracted by the Faculty – Kosovo University Clinical Centre.

The study program abides by the minimum requirements of the Kosovo Qualification Framework. The content of the curricula is modelled on the basis of best practice from International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and European Federation of Clinical Chemistry and Laboratory Medicine (EFCC).

Compliance with particular KAA standards:

Standard 1.1. The institution has a defined mission statement that includes three main pillars: teaching, research and community service. **YES**

Standard 1.2. The mission of the institution has been defined and, if the case, revised, based on a consultation process involving external and internal stakeholders. **YES**

Standard 1.3. In discussions during the visit some participants did not demonstrate complete understanding of the mission. *From the published document the mission could be easily recognized by the members of the academic community of the institution.* **Partially YES**

Standard 1.4. The institutional mission provides an effective guide for strategic planning, decision making and operations of the institution. **YES**

Standard 1.5. Medium and long term institutional objectives are consistent with and support the mission. **YES**

General compliance level: 100% fully compliant

2.2. Quality management

The overall quality assurance policy and procedure is based on *UBT Quality Manual*.

According to SER some of the strategic goals of UBT College are:

- Achieving Academic Excellence - The institution aspires excellent quality standards and consistent active learning approaches which offer authentic experiences and an inspiring, values-based learning environment to a diversity
- Developing Research, Innovation and Social Responsibility - Offer innovative ways for learners, spin-in and spin-out companies as well as external clients to engage with enterprise supports and applied research, thus creating new knowledge and new employment.

- Creating a Positive Working and Learning Environment - Creating a Positive Working and Learning Environment Aims to offer a high-quality and supportive working and learning environment for all types of students (full-time, part-time, priority groups) and staff.
- Maintaining and increasing internationalization and regional partnerships - Maintaining and increasing internationalization and regional partnerships Formation of the new local and international higher education alliances and continued excellent performance against international and regional efficiency and effectiveness benchmarks.
- Partnering with the community - Partnering with the community Will continue to forge strong links with industry and wider society, which will be supported through mainstream funding, alternative income streams and volunteering arrangements in order to provide service to industry and the community at institutional, staff and student level

Those strategic goals of UBT College normally applies also to Faculty of Laboratory Technician.

The Faculty undertakes a periodic evaluation of programmes once every three years. The evaluation process serves to review the programme learning outcomes, programme teaching and learning methodology, assessment and its courses. The evaluation process also reviews the programme outcomes, graduates and impact in the industry and community. The process is composed of: programme self-evaluation, programme strategy and proposed revisions document

Compiance with particular KAA standards

Standard 2.1. The institution has a strategic plan for a period of minimum three years or longer with prediction of further technological development **YES**

Standard 2.2. The strategic plan is drafted in close consultation with the academic community at the institution, as well as external stakeholders and private sector. ***YES***

Standard 2.3. Strategic planning seems to be integrated with annual and longer term budget processes that provide for regular adjustments. ***YES***

Standard 2.4. In economical and political environment of Kosovo The strategic plan takes as much as possible realistic account of aspects of the internal and external environment affecting the development of the institution. ***YES***

According to Standard 2.5. The implementation of the strategic plan is monitored on short and medium term targets, and outcomes are evaluated. This is partially present in a document but reliable methodological details is not easy to develop **YES**

Standard 2.6. The institution has a decision making system and internal operating regulations in conformity with current legal provisions. ***YES***

Standard 2.7. The election criteria and processes of the decision makers and other elected positions are clear, transparent and published in institutional regulations. ***YES***

Standard 2.8. The responsibilities of the decision making bodies are defined in such a way that the respective roles and responsibilities for overall policy and accountability, the senior administration for management, and the academic decision making structures are clearly differentiated and followed in practice. ***YES***

Standard 2.9. Student representatives are members of all decisional, executive and consultative bodies. The mechanism for electing student representatives is clearly explained in internal regulations. There is a democratic, transparent and non-discriminatory election procedure that does not limit students right to represent and to be represented. The institution is not

involved in the process of electing student representatives. Some individual students are not completely aware or not interested of that **partially *YES***
Standard 2.10. The higher education institution has an administration that is effective in terms of organization, staffing levels and qualifications, and functions rigorously. YES
*Standard 2.11. The responsibilities of administrative staff are clearly defined in position descriptions and they match the qualifications of the individual. **YES***

Compliance level: 98% fully compliant

2.3. Academic Staff

SER contains a list of 35 academic staff. Of those 32 are PhD holders.
The staff members assigned in the curricula as Subject Leaders cover nearly 80 percent of the teaching workload.

Staff development component was focused on providing effective pedagogical skills. Pedagogical skills training for the Faculty has focused on the following topics: student-centred learning, curriculum design, writing learning outcomes, lesson planning, design and delivery, group learning, problem based and project based learning, E-learning, Assessment and integrating key skills into the curriculum

Compiance with particular KAA standards
Standard 3.1. Candidates for employment are provided with full position descriptions and conditions of employment. To be presented in tabular form data about full time (FT) and part time (PT) academic/ artistic staff, such as: name, qualification, academic title, duration of official (valid) contract, workload for teaching, exams, consulting, administrative activities, research, etc. for the study program under evaluation **YES**
Standard 3.3. Academic staff do not cover, within an academic year, more than two teaching positions (one full-time, one part-time), regardless of the educational institution where they carry out their activity. **YES**
Standard 3.4. At least 50% of the academic staff in the study program are full-time employees and account for at least 50% of the classes of the study program. **YES**
Standard 3.2. The teaching staff must comply with the legal requirements concerning the occupation of teaching positions included in the Administrative instruction on Accreditation.
Standard 3.5. For each student group (defined by the statute of the institution) and for every 60 ECTS credits in the study program, the institution has employed at least one full-time staff with Ph.D. title or equivalent title in the case of artistic/applied science institutions. **YES**
Standard 3.6. Opportunities are provided for additional professional development of teaching staff, with special assistance given to any who are facing difficulties. **YES**

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Standard 3.7. The responsibilities of all teaching staff, especially full-time, include the engagement in the academic community, availability for consultations with students and community service. **YES**
Standard 3.8. Academic staff evaluation is conducted regularly at least through self-evaluation, students, peer and superiors' evaluations, and occur on a formal basis at least once each year. The results of the evaluation are made publicly available. **YES**
Standard 3.9. Strategies for quality enhancement include improving the teaching strategies and quality of learning materials. **NO**
Standard 3.10. Teachers retired at age limit or for other reasons lose the status of full-time teachers and are considered part-time teachers. **NO** *(not applicable?)*

Compliance level: 95% fully compliant

2.4. Educational process content

According to SER The study lasts three years or 180 ECTS (p. 384)

According to SER students learning outcomes and key competences are harmonised with the European Federation of Clinical Chemistry and Laboratory Medicine Guidelines for generic education in laboratory medicine.

The study program aims to provide the students with both theoretical knowledge as well as clinical and managerial skills via range of activities such as: theoretical instruction, participating in laboratory, participating in multidisciplinary meetings at which biochemical and haematological results are presented and discussed in light of various clinical cases, attending clinics at which patients are being investigated for disease of major organ function, generating a portfolio of clinical cases involving each of the major areas of laboratory testing. The practical work is primarily organised in cooperation with University Clinical Centre and Ministry of Health through an Agreement for Access to Clinics' Facilities.

Students assessment of theoretical and clinical experience include:

- Internal formal examination
- Direct observation
- Multi-source feedback – capturing others' perception of the trainee's knowledge, skills, competence, attitude, behaviour, learning need and potential.
- Case-based discussion
- Use of personal portfolios
- Evaluation of written output – examples include the thesis evaluation

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The program is completed by passing all the required exams and by completing the final paper/final exam. Student graduation is conditional upon meeting all course requirements of the mandatory and the elective courses and has attained the required ECTS. Diploma thesis is registered in the final year of studies. The diploma thesis evaluation committee, responsible for assessing the diploma thesis and conducting the exam, is appointed by the Vice-Dean for Teaching. Upon successfully completing all the exams and having met all the course requirements including the production and presentation of the diploma thesis, each student is conferred the degree.

Year I, Semester 1 (30 ECTS): Anatomy and Physiology, Biology and Human GeneticsChemistry I (General and Inorganic), Biophysics, Medical Ethics and Legislation,
Elective: English 1, German 1, Elective 1, Academic Writing, Research Methods

Semester 2 (30 ECTS): Biochemistry I, Histology and Embryology, Introduction to Medical Laboratory, Chemistry II (Analytical), Public Health and Hygiene, Health Psychology, Medical Informatics
Elective: English 2, German 2

Year II, Semester 3 (30 ECTS): Biochemistry II, Pathophysiology, Microbiology and Immunology, Histopathology, Hematology I, Practice I
Elective: History of Medicine, Health Sociology

Semester 4. (30 ECTS): Biochemical Analysis I, Medical Bacteriology and Virology, Hematology II; Practice II, Transfusion Medicine, Communication Skills, Occupational and Lab Safety
Elective: Emergency Medicine, Radiology

Year III, Semester 5 (30 ECTS): Cytology and Cytodiagnostics, Biochemistry Analysis II, Epidemiology, Molecular Biology Techniques, Nuclear Medicine, Practice III
Elective: Toxicology, Immunology

Semester 6 (30 ECTS): Practice IV, Clinical Pharmacology, Medical Lab Management Quality Control in Laboratory, Biostatistics
Elective: Digital Molecular Imaging, Lab in Vitro Cells Methods
Thesis

ET recommendations:

- Syllabus *Biostatistics* describe in fact course on physics
- In syllabus *Biology and human Genetics* there is a statement that *The course is designed to teach dental medicine students about the basic concepts of the contemporary biological science* etc

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- Syllabus *Biophysics* contains the same description as syllabus Biostatistics
- Syllabus *Health Psychology* describes is in a fact basis of psychiatry. Practical include:
- Schizophrenia – practical presentation and exercise with a patient
- Mood disorders – practical presentation and exercise with a patient or
- Mental retardation – practical presentation and exercise with a patient
- Such patient presentation in front of students to be lab technicians is ethically questionable
- Equipment: Pc/Projector, Laboratory full equipment
- Course leader is psychologists with a PhD in Public Health. CV does not mention experience in clinical psychiatry. No publication in PubMed or Google scholar.
- Description of the course English starts with the claim: *The aims of the course are as follows: to learn and acquire a very specialist vocabulary used in **dental medicine**; to get familiar with the English word formation in **dental medicine,***
- **Clinical pharmacology** – there is no justification o the title (no pharmacotherapy) it is just Pharmacology
- **Practically all textbooks are in English and some in Croatian. They ae not always best choice for student of Laboratory medicine, for example:** *Mejovšek, M. (2013). Metode znanstvenog istraživanja u društvenim i humanističkim znanostima. Naklada Slap, Jastrebarsko. (Research methods in social and humanistic sciences)*
- Good Clinical Laboratory Practice (GLP) should be one of the core mandatory module of the study of Laboratory Medicine. There are number of documents even textbooks (from NIH, EMA, WHO etc.) available on Internet.
- Syllabus on ethics should include bioethics and research ethics

Compliance with particular KAA standards

Standard 1.4*. There are formal policies, guidelines and regulations dealing with recurring procedural or academic issues. These are made publicly available to all staff and students.* ***NO*** *(or partially)*

Standard 1.5. *All staff and students comply with the internal regulations relating to ethical conduct in research, teaching, assessment in all academic and administrative activities.* ***YES***

Standard 1.6. *All policies, regulations, terms of reference and statements of responsibility relating to the management and delivery of the program are reviewed at least once every two years and amended as required in the light of changing circumstances.* ***YES***

Compliance: 66% Substantially complied

2.5. Students

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Candidates for admission. Only students that have completed at least two years of prior education in medicine, biology, physics and chemistry at upper secondary school level will be considered for admission. A candidate should: (a) have passed the high school national examination, with Physics, Chemistry, Biology and English being key requirements. Successful applicants should have achieved 40% or higher national Matura examination in these subjects. Additionally, students should be at least 17 years of age at the time of application and should demonstrate that they are medically and legally fit for the profession

Admission to the study is performed on the basis of a public call and the conducted entrance examination. The entrance examination is conducted by the Commission for the Entrance
the results of the entrance examination, the Commission creates a ranking list determining which candidates have become entitled to enrol on the basis of the results achieved in the entrance examination and who have psychophysical abilities for the title of a doctor of dental medicine (Copy paste error?).

The study methods and requirements for course completion will always be specified in the course syllabus available to the students before the course starts. Each course has a detailed syllabus, which is more detailed than a course programme and describes topics to be covered during the course – objectives, subject content for each week, organization of work, requirements for seminar and individual work, gives a list of required and recommended reading and sets of attendance and specific assessment rules.

Student's knowledge assessement will be performed continually during the coursework and at the end of each course. During an exam the overall knowledge acquired in the course of the teaching process and represented by a single course of more related courses is tested. Exams are obligatory for all the mandatory and elective courses, by definition exams are public except for the practical parts.

Courses are described before.

Faculty Code of Ethics and Student Conduct regulates students expected standards of behaviour during education, examination and written assignments

Compliance with particular KAA standards:

Standard 5.1. There is a clear and formally adopted admission procedure at institutional level that the study program respects when organising students' recruitment. Admission requirements are consistently and fairly applied for all students. **Compliance: YES**

Standard 5.2. All students enrolled in the study program posses a high school graduation diploma or other equivalent document of study, according to MEST requirements. **YES**

Standard 5.3. The study groups are dimensioned so as to ensure an effective and interactive teaching and learning process. **YES**

Standard 5.4. Feedback to students on their performance and results of assessments is given promptly and accompanied by mechanisms for assistance if needed. **YES**

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Standard 5.5. The results obtained by the students throughout the study cycles are certified by the academic record. **YES**
Standard 5.6. Flexible treatment of students in special situations is ensured with respect to deadlines and formal requirements in the program and to all examinations. **YES**
Standard 5.7. Records of student completion rates are kept for all courses and for the program as a whole and included among quality indicators. **YES**
Standard 5.8. Effective procedures are being used to ensure that work submitted by students is original. **YES**
Standard 5.9. Students' rights and obligations are made publicly available, promoted to all those concerned and enforced equitably; these will include the right to academic appeals. **YES**
Standard 5.10. The students' transfer between higher education institutions, faculties and study programs is clearly regulated in formal internal documents. **YES**
Standard 5.11. Academic staff is available at sufficient scheduled times for consultation and advice to students. Adequate tutorial assistance is provided to ensure understanding and ability to apply learning. **YES**

Compliance level: Fully compliant
ET recommendations: *None*

2.6. Research

The main research themes of the Medical Laboratory program are:

- *Personalised Patient Care.* This research theme is implemented collaboratively with the Faculty of Nursing, Faculty of Pharmacy, Faculty of Food Science and Technology, Faculty of Mechatronics and Faculty of Computer Science and Engineering.

- *Diagnostic Molecular Imaging.*

- *Computational modelling* - The long-term objective is is developing the capability to collect annotated imaging, clinical and molecular data, and integrate them by creating databases that encode the relationships among them.

- *Genetics, Genomics and Cytogenetics*–investigation and management of genetic and genomic disorders, genetic and genomic disorders and their impact on patient and their families and Scientific basis of inherited and sporadic cancers.

- *Epidemiology and health protection* –epidemiological consequences of hospital-acquired and community disease control with reference to tuberculosis, viral hepatitis, HIV and genitourinary disease, decontamination, disinfection and sterilisation in the hospital, laboratory and primary care setting, water safety within the healthcare setting, Legionella, Pseudomonas, M. chimera, environmental outbreaks, e.g. Legionella, Norovirus

- *Haematology and Blood Transfusion* - symptoms, pathogenesis and laboratory investigation of anaemia (including erythrocytes membrane and enzyme abnormalities

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and status of iron, vitamin B12, folate, metabolite etc.), symptoms, pathogenesis and laboratory investigation of haemato-oncological abnormalities (including leukaemias, myeloproliferative disorders, lymphomas, multiple myelomas, myelodysplastic syndrome etc.), haematological, immunological, microscopic, cytogenetic and molecular methods used in the diagnostics of haematological disorders, along with interpretation of obtained results and role and strategy of the laboratory diagnostics in haematological diseases diagnosing, differentiating, monitoring and evaluating the effects of treatment

Staff productivity. The Year-End Review creates a record of staff productivity in research, teaching, service and administration.

UBT clearly defines research outcomes as

- Articles published in indexed journals
- Conference papers
- Proceedings and
- Books.

Research grants of up to 1000 Euro are considered for each research cluster seeking external funding opportunities. Another lump sum of 5000 Euro annually is left for staff conference and research presentation support. Research clusters may apply for research assistantship grants of up to 2000 Euro annually to involve undergraduate students in support of their research and to provide a useful learning opportunity for the students

Internatonal visibility. Out of 28 permanent staff members and 3 part-time SER individually shows 5 teachers in a tabular form. Those 5 teachers have teaching experience but research experience is limited. Internationally visible (In PubMed as the most important data base) one can found only two teacher, but with address that is not UBT College (obviously research was not done at UBT College). Other researchers have primarily only abstracts at international meetings. In natural sciences such abstract are usually selected only based on formal evaluation they should not be considered equal to international publications.

Compliance with particular KAA standards:

Standard 6.1. The study program has defined scientific/applied research objectives (on its own or as part of a research centre or interdisciplinary program), which are also reflected in the research development plan of the institution; sufficient financial, logistic and human resources are allocated for achieving the proposed research objectives. **YES**

Standard 6.2. Expectations for teaching staff involvement in research and scholarly activities are clearly specified, and performance in relation to these expectations is considered in staff evaluation and promotion criteria. **NO**

Standard 6.3. Clear policies are established for defining what is recognized as research, consistent with international standards and established norms in the field of study of the program. **YES (partially consistent with international standards)**

Standard 6.4. The academic staff has a proven track record of research results on the same topics as their teaching activity. **YES (only part of academic staff)**

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Standard 6.5. The academic and research staff publish their work in speciality magazines or publishing houses, scientific/applied/artistic products are presented at conferences, sessions, symposiums, seminars etc. and contracts, expertise, consultancy, conventions, etc. are provided to partners inside the country and/or abroad. **NO**
Standard 6.6. Research is validated through: scientific and applied research publications, artistic products, technological transfer through consultancy centres, scientific parks and other structures for validation. **NO**
Standard 6.7. Each academic staff member and researcher has produced at least an average of one scientific/applied research publication or artistic outcome/product per year for the past three years. **YES**
Standard 6.8. Academic and research staff publish under the name of the institution in Kosovo they are affiliated to as full time staff. NO
Standard 6.8. Academic staff are encouraged to include in their teaching information about their research and scholarly activities that are relevant to courses they teach, together with other significant research developments in the field. YES
Standard 6.9. Policies are established for ownership of intellectual property and clear procedures set out for commercialization of ideas developed by staff and students. **YES**
Standard 6.10. Students are engaged in research projects and other activities. YES

Compliance level: 60% Partially compliant

ET comments and recommendations:

- From young bachelor student of Medical Laboratory one can hardly expect any individual/ independent research projects However they might be a part of larger reteach teams.
- Some of suggested research themes are not appropriate for students of Laboratory Medicine (notorious example could be Diagnostic Molecular Imaging).
- Conference proceedings, abstracts at international meetings etc. are usually selected only on formal ground they should not be considered international publications.

2.7. Infrastructure and resources

The premises of the Laboratory Technician Program are situated in the UBT Innovation Campus Lipjan. The institution operates in a medium-size modern facility build in 2017. The premises were constructed and tailored for higher education purposes. The Faculty premises includes 4 four auditoriums and 9 smaller seminar rooms and 18 policlinics. In addition, it has designated office space for staff and students. A videoconferencing auditorium has been arranged in 2017 with technical aids, conference equipment, a television set, a video projector and a smart board. The Faculty also has printing and photocopy equipment for students. The faculty has a computer laboratory equipped with 52 computer PC and 8 notebooks.

Space and Facilities, Laboratories, Equipment and IT are presented in details (including number of some glassware, which is not necessary). Equipment of Laboratory Medicine seems to be the same as equipment for other health sciences at UBT College.

The library section includes ten seats and over 1200 books designated for different subjects.

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Compliance with particular KAA standards

Standard 10.1. Adequate financial resources are provided for acquisitions, cataloguing, equipment, and for services and system development. **YES,**
Standard 10.2. Books, journals and other materials are available in English (or other languages) as required for programs and research organised at the institution. **YES** *(although learning material in Albanian language practically does not exist)*
Standard 10.3. Reliable and efficient access to online databases, research and journal materials relevant to the institution programs is available for users **YES**
Standard 10.4. Adequate facilities are provided to host learning resources in a way that makes them readily accessible. Up to date computer equipment and software are provided to support electronic access to resources and reference material. **YES**
Standard 10.5. Library and associated facilities and services are available for extended hours beyond normal class time to ensure access when required by users. **YES**
Standard 10.6. Reliable systems are used for recording loans and returns, with efficient follow up for overdue material. Effective security systems are used to prevent loss of materials. **NA** *(not assessed)*
Standard 10.7. The institution provides an adequate, clean, attractive and well maintained physical environment of both buildings and grounds. Facilities fully meet Kosovo legislation on health and safety. **YES**
Standard 10.8. Quality assurance processes used include both feedback from principal users about the adequacy and quality of facilities, and mechanisms for considering and responding to their views. **YES**
Standard 10.9. Appropriate provision for both facilities and learning resources is made for students and staff with physical disabilities or other special needs (such as visual or hearing impairments). **NO**
Standard 10.10. Complete inventories are maintained of equipment owned or controlled by the institution including equipment assigned to individual staff. Space utilization is monitored and when appropriate facilities reallocated in response to changing requirements. **YES**
Standard 10.11. Adequate computer equipment is available and accessible for teaching, staff and students throughout the institution. The adequacy of provision of computer equipment is regularly evaluated through surveys or other means. **YES**
Standard 10.12. Technical support is available for staff and students using information and communications technology. Training programs are provided to ensure effective use of computing equipment and appropriate software for assessments, teaching and administration. **YES**

Compliance level: 95% fully compliant
ET recommendations: *None*

ANNEXES

According to SER: By the end of the program, the laboratory technician should be able to assess, plan, deliver, interpret, effectively communicate with clinicians' and evaluate high quality clinical services that are targeted to meet the needs of individuals and groups of patients. This Annexes contains:

4.3.9 Annex 1: Course Description (probably refers to Syllabus document)

4.3.10 Annex 2: Diary Log Sheet of Practical Experiences (for students to record all practical experience completed throughout the training.)

4.3.11 Annex 3: General Competences Book

Containing: 1. *Basic knowledge requirements, Indications for laboratory medicine, Influence of collection and storage of specimens, Analytical principles and techniques etc.*

- Those requirements are listed in a table with general term Generic Knowledge (would be better to name that list Specific or Professional Knowledge because for example Quantitative PCR techniques (real time PCR techniques, digital PCR

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techniques) cannot be considered as generic knowledge. As a list of professional knowledge requirement this annex is most important part of SER. However some of those "generic knowledge" is difficult to find in syllabus of particular teaching courses (Syllabus document).

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3. OVERALL EVALUATION AND RECOMMENDATION OF THE ET

SER is composed in logical order following KAA standards. However SER as well as Syllabus document contains many serious errors mentioned in this report. Visit to UBT was useful to obtain realistic view of the program.

Recommendation of the Expert Team 2019

A. Only a small fraction of teaching staff has research publications in internationally visible medical journal. UBT College should develop all possible measures to make its research internationally visible:

1. Create a research plan for the study program – clear research objectives, research themes and resources.
2. Motivate academic staff to increase research production by considering research results as more important promotion criterion;
3. Include in the Program visiting professors especially distinguished scientist from Kosovo working in known universities abroad. Involvement of such foreign experts should not be restricted only to education but to research projects as well.

B. One of the core course in Laboratory Medicine should be Good Laboratory Practice. This is not present in program proposal.

C. On several places in SER or Syllabus one can find that SER is about Dentistry and not Laboratory Medicine program.

D. There is practically no any textbook or other learning document in Albanian language. Attempt to speak with randomly approached students on the corridor showed that some students do not speak English at al. Under such circumstances it is not clear how students will learn and prepare exams.

E. Document Syllabus raises some concerns because it seems that it is not prepared as it might be expected from academic institution.

a. **Syllabus Biostatistics** describe in fact course on physics
b. In syllabus Biology and human Genetics there is a statement that *The course is designed to teach dental medicine students about the basic concepts of the contemporary biological science* etc.
c. Syllabus Biophysics contains the same description as syllabus **Biostatistics**

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d. **Syllabus Health Psychology** describes primarily basis of psychiatry. Practical include:
   Schizophrenia – practical presentation and exercise with a patient
- Mood disorders – practical presentation and exercise with a patient or
- Mental retardation – practical presentation and exercise with a patient

There is no any comment on complex problem if informed consent of psychiatric patients. Such patient presentation in front of students, future lab technicians, is ethically questionable (see APENDIX).

In response to mentioned questions EC received unified document named: *Integrated Studies in Pharmacy / Laborant of Biochemical Medicine BSc*, like it is one and not two programs. Program Integrated Studies in Pharmacy complies with KAA standards and a Integrated Studies in Pharmacy and in UBIT response it is evident that errors will be corrected. From unified document it is not always clear what applies to one and what to second program. However in this unified document there are no specific comments concerning *Laborant of Biochemical Medicine BSc*. Major problem in that program is public exposure of psychiatric patients. This was clearly expressed in preliminary EC report. As additional explanation in interim report (named extended report) appendix WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects was included. However, in UBT response this problem is not mentioned at all.

In conclusion program *Laborant of Biochemical Medicine BSc* offered by UBT College contains Practical that is ethically questionable. UBT College was clearly notified in preliminary and in interim EC report. However, in UBT response this problem is not mentioned at al. Consequently EC CANNOT RECOMMEND program that contains ethically questionable Practical.

Expert Team

Chair

(Signature) (Print Name) (Date)

Member

(Signature) (Print Name) (Date)

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Member

(Signature)	(Print Name)	(Date)

Member

(Signature)	(Print Name)	(Date)

Member

(Signature)	(Print Name)	(Date)

Member

(Signature)	(Print Name)	(Date)

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APENDIX:

WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

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Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Preamble

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1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.

The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.

2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

General Principles

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."

4. It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.

6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.

8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent.

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement

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should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

11. Medical research should be conducted in a manner that minimises possible harm to the environment.

12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.

14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, Burdens and Benefits

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

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Vulnerable Groups and Individuals

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

Scientific Requirements and Research Protocols

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

Research Ethics Committees

23. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor and any other undue influence and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by

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the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

Privacy and Confidentiality

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

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29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Use of Placebo

33. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:

Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or

Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention

and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

Extreme care must be taken to avoid abuse of this option.

Post-Trial Provisions

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34. In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Research Registration and Publication and Dissemination of Results

35. Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

Unproven Interventions in Clinical Practice

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available.

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