



**COMPANY  
PROFILE**



**ECOLI**

# Ecoli Dx at a Glance

## Development – Manufacture – Sale – Support

**Independent company**, part of DYNEX group

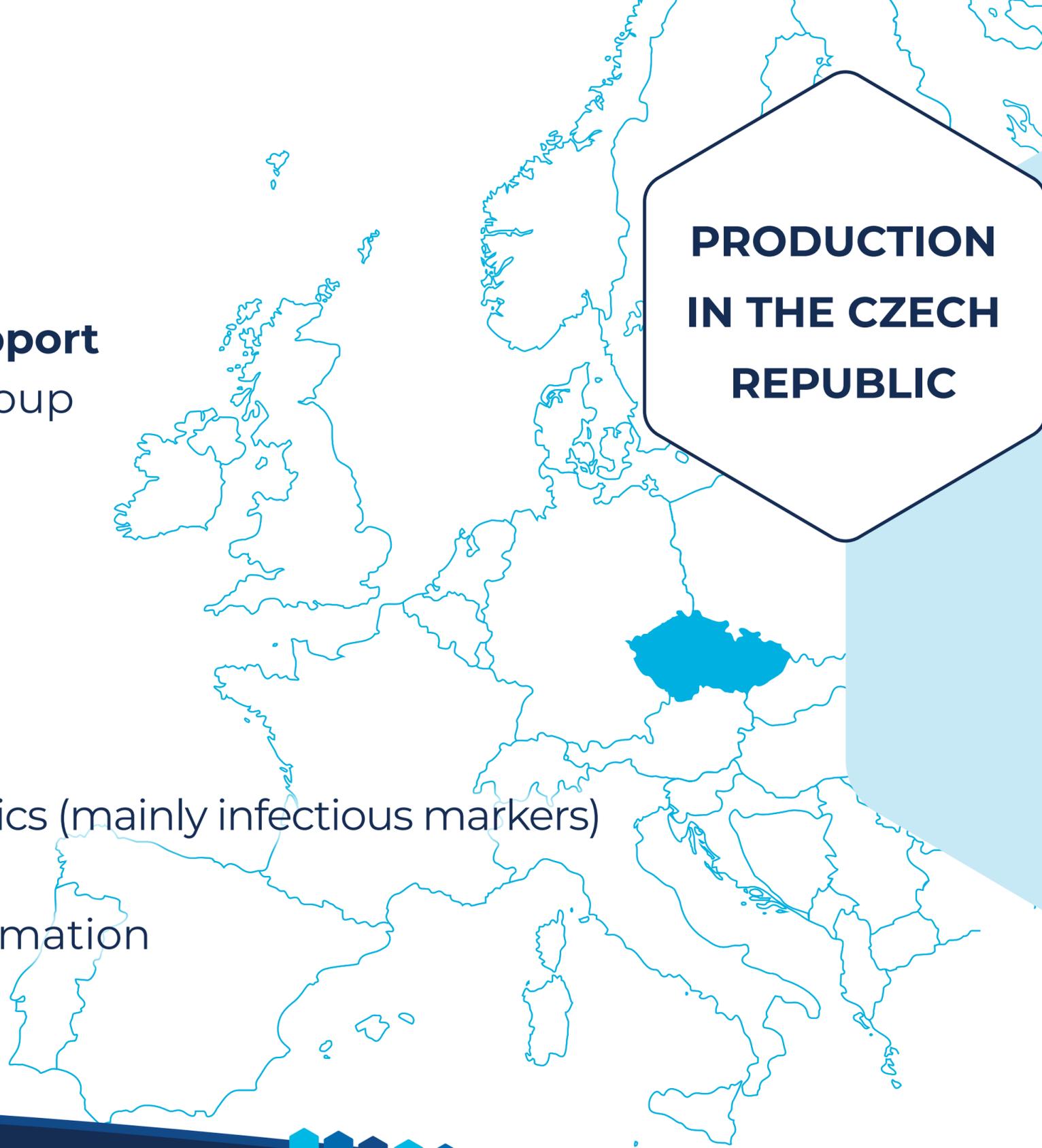
- 20+ years of history
- 20+ professionals
- 30+ distributors

**European** based, worldwide standards

- ISO 13845:2016 certified

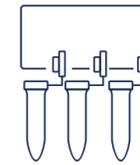
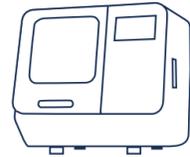
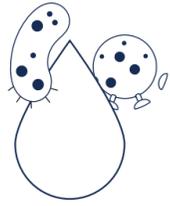
## 200+ products

- Real-Time PCR kits for human diagnostics (mainly infectious markers)
- Nucleic acid extraction kits
- Associated instrumentation and automation



**PRODUCTION  
IN THE CZECH  
REPUBLIC**

# Complete solution for PCR diagnostics of infectious diseases from A to Z



 AmpliSens®



:EPure

 AmpliSens®



:EDetect

:EQuantix

:ESens

 AmpliSens®

- **Large investments to R&D**
  - Transition to in-house production
  - Robust development pipeline





- Developed and produced by the CRIE in Moscow
- Ecoli Dx is the authorized representative all over the world, **with exclusivity in EU**
- **100+ Real-Time PCR kits**
  - A to Z of all infectious diseases and genetic markers
  - Known for their high sensitivity, specificity, and reasonable pricing
  - CE IVD certification of all previously CE IVD marked PCR kits expired
    - all of them available as RUO now
- Supplementary PCR reagents and **manual extraction kits**
  - Certification had been updated and available as CE IVD-R marked

# eSens introduction

- Produced by Ecoli Dx near Prague in CZ
- „European AmpliSens“
  - **original AmpliSens® chemistry**
    - The same polymerases
    - The same primers, probes and solutions
    - The same protocols
    - Only different packaging, labeling and documentation
  - **CE IVD-D marked** → Seamless transition AmpliSens® to eSens
    - Maintain AmpliSens workflow unchanged while retaining CE IVD compliance
    - Except PCR kits classified in group D according to IVDR criteria, which are supplied as RUO now
- **80+ Real-Time PCR kits**
  - A to Z of all infectious diseases and genetic markers
  - Keeping AmpliSens performance and reasonable pricing



see  
AmpliSens – eSens  
conversion chart

# eSens remarks

- **eSens NA kits**  
**„NA“ for Non-AmpliSens chemistry**
  - eSens NA RespiViral Multiplex
  - eSens NA SARS-CoV-2/Influenza A/B Multiplex
  - eSens NA SARS-CoV-2/SARS-CoV Multiplex
  - eSens NA Mycosis Multiplex
- **C. trachomatis or CMV detection available as RUO only**
  - IVD certification valid only for other parameters in the multiplex assays
  - Additional instructions for the RUO detection of CT or CMV not included in the IFU
  - Application notes available separately
- **PCR kits classified in group D according to IVDR criteria are supplied as RUO now**
  - kits targeting SARS-CoV-2, CCHFV, EBOV Zaire, Plasmodium sp., B. anthracis
  - kits targeting SARS-CoV, Influenza A/H5N1, CCHFV, EBOV Zaire, Plasmodium sp., B. anthracis

Inquire the new equivalent eSens kit	
ES3122B	eSens HCV genotype QL PCR kit
ES3112B	eSens HBV genotype QL PCR kit
ES3402B	eSens Listeria monocytogenes QT PCR kit
ES3810A	eSens Streptococcus pyogenes QT PCR kit
ES3081A	eSens HPV HR 14 genotype QT PCR kit
ES3080A	eSens HPV HR 14 screen/16,18,45 genotype QT PCR kit
ES3605B	eSens Zika virus QL PCR kit
ES3207A	eSens HHV7 QT PCR kit
ES3441A	eSens JCV/BKV QT PCR kit
ES3606B	eSens Yellow fever virus QL PCR kit
ES3400B	eSens Enterovirus QL PCR kit
ES3701B	eSens Borrelia miyamotoi QL PCR kit
ES3501B	eSens Helicobacter pylori QL PCR kit
ES3308A	eSens Corynebacterium diphtheriae/tox genes QL PCR kit
ES3208A	eSens HHV8 QT PCR kit
ES3306B	eSens MDR MTC QL PCR kit
ES3009B	eSens M.genitalium ML/FQ resistance QT PCR kit
ES3640B	eSens Plasmodium sp./falciparum/vivax QL PCR kit <b>RUO now (group D)</b>
ES4303A	eSens MDR VRE QL PCR kit
ES4304A	eSens MDR MCR-1 QL PCR kit
ES3807B	eSens Brucella sp. QL PCR kit
ES3040A	eSens Ureaplasma parvum/urealyticum QL PCR kit
ES3001A	eSens Treponema pallidum QL PCR kit
ES3440B	eSens N.meningitidis/H.influenzae/S.pneumoniae QL PCR kit
ES3007A	eSens Ureaplasma sp. QL PCR kit
ES3700B	eSens Borrelia burgdorferi sI QL PCR kit
ES3004A	eSens Mycoplasma hominis QL PCR kit
ES3806B	eSens Bacillus anthracis QL PCR kit <b>RUO now (group D)</b>
ES3541B	eSens Acute intestinal infections QL PCR kit

the table continues →

Inquire the new equivalent eSens kit	
ES3808B	eSens Leptospira QL PCR kit
ES3003A	eSens Mycoplasma genitalium QL PCR kit
ES3307B	eSens Legionella pneumophila QT PCR kit
ES3000A	eSens Neisseria gonorrhoeae QL PCR kit
ES3305B	eSens MTC QL PCR kit
ES3048A	eSens Ureaplasma/M.genitalium/M.hominis QL PCR kit <b>C.trachomatis RUO*</b>
ES3050A	eSens N.gonorrhoeae/M.genitalium/T.vaginalis QL PCR kit <b>C.trachomatis RUO*</b>
ES3542B	eSens Escherichioses QL PCR kit
ES3049A	eSens N.gonorrhoeae /M.genitalium QL PCR kit <b>C.trachomatis RUO*</b>
ES3002A	eSens Trichomonas vaginalis QL PCR kit
ES3044A	eSens Florocenosis/Bacterial Vaginosis QT PCR kit
ES3045A	eSens Florocenosis/Mycoplasmas QT PCR kit
ES3809A	eSens Streptococcus agalactiae QT PCR kit
ES4300A	eSens MRSA QT PCR kit
ES3005A	eSens Gardnerella vaginalis QL PCR kit
ES3043A	eSens Gardnerella vaginalis/Lactobacillus sp. QT PCR kit
ES3309B	eSens Mycobacterium tuberculosis/bovis/BCG QL PCR kit
ES3300A	eSens Bordetella pertussis/bronchiseptica/parapertussis QL PCR kit
ES3047A	eSens Florocenosis/Aerobes QT PCR kit
ES4301A	eSens MDR MBL QL PCR kit
ES4302A	eSens MDR KPC/OXA QL PCR kit
ES3006A	eSens Candida albicans QL PCR kit
ES3803B	eSens Pneumocystis jirovecii QL PCR kit
ES3041A	eSens Candida albicans/glabrata/krusei QL PCR kit
ES3804A	eSens Cryptococcus neoformans QL PCR kit
ES3046A	eSens Florocenosis/Candida QT PCR kit
ES3206A	eSens HHV6 QT PCR kit
ES3090A	eSens HPV LR 6/11 genotype QL PCR kit
ES3082A	eSens HPV HR 16/18 genotype QT PCR kit
ES3603B	eSens CCHFV QL PCR kit <b>RUO now (group D)</b>
ES3150B	eSens HGV QL PCR kit
ES3301B	eSens Influenza virus A H5N1 QL PCR kit <b>RUO now (group D)</b>
ES3201A	eSens HSV 1/2 genotype QL PCR kit
ES3100B	eSens HAV QL PCR kit
ES3540B	eSens Rotavirus/Norovirus/Astrovirus QL PCR kit
ES3240A	eSens EBV/HHV6 QT PCR kit <b>CMV RUO*</b>
ES3801B	eSens Parvovirus B19 QT PCR kit
ES3702A	eSens TBEV QL PCR kit
ES3602B	eSens WNV QL PCR kit
ES3304A	eSens ARVI screen QL PCR kit
ES3401B	eSens Poliovirus QL PCR kit
ES3740A	eSens TBEV/Borrelia/Anaplasma/Ehrlichia QL PCR Kit
ES3202B	eSens VZV QL PCR kit
ES3601B	eSens Dengue virus type QL PCR kit
ES3303B	eSens Influenza virus A H5/H87/H9 QL PCR kit
ES3083A	eSens HPV HR 14 genotype QT PCR kit, variant 4C
ES3604B	eSens EBOV Zaire QL PCR kit <b>RUO now (group D)</b>
ES3200A	eSens HSV QL PCR kit
ES3203A	eSens EBV QT PCR kit
	eSens F2/F5 SNP PCR kit

# eDetect Advanced PCR Diagnostic Line

- **Our main and most advanced PCR diagnostic line**
- First eDetect kits are to be launched in **Q1-Q2/2027**
- **Developed and produced completely by Ecoli Dx**
  - Our own chemistry
  - Raw materials with EU origin only (mainly CZ, DE)
  - Production in our facility - absolute control over quality
    - Improved warranty and support
    - Short lead times and responsiveness to specific demands
- All kits to be CE marked (EU) 2017/746 **(IVD-R)**
  - RUO versions will also be available



# eDetect main features

## DOUBLE CONTROL OVER QUALITY

EXO-IC: internal exogenous control

ENDO-IC: internal endogenous control



## FAST AND CONVENIENT ASSAY SETUP

Lyophilized polymerase

Provided in 2 separate tubes (2x25 reactions) – rehydrate them as you need

One-step preparation of the mastermix

Hot Start polymerase – assay setup at room temperature



## PROTECTION AGAINST CONTAMINATION

UDG enzyme to prevent carryover contamination from previous PCR runs

In polymerase mix



## ACCURATE SAMPLE QUANTIFICATION

4 standards included in quantitative assays

Easy-to-use quantification mixes



## USE ANY REAL-TIME PCR INSTRUMENT

Validated on CFX Opus 96 and RGQ

Can be used on other PCR instruments

Any type of PCR plastic



## UNIFIED PCR THERMAL CYCLING PROTOCOLS

You can combine different eDetect assays within one run



## CONVENIENT SHIPPING AND STORAGE

Transport possible at room temperature

Long shelflife (aiming for 24 months)



# eDetect Roadmap 2027/28

## HCV & HBV

- Hepatitis C virus QT\*
- Hepatitis B virus QT\*

## TORCH

- Toxoplasma gondii QL\*
- Rubella virus QL\*
- Parvovirus B19 QL\*

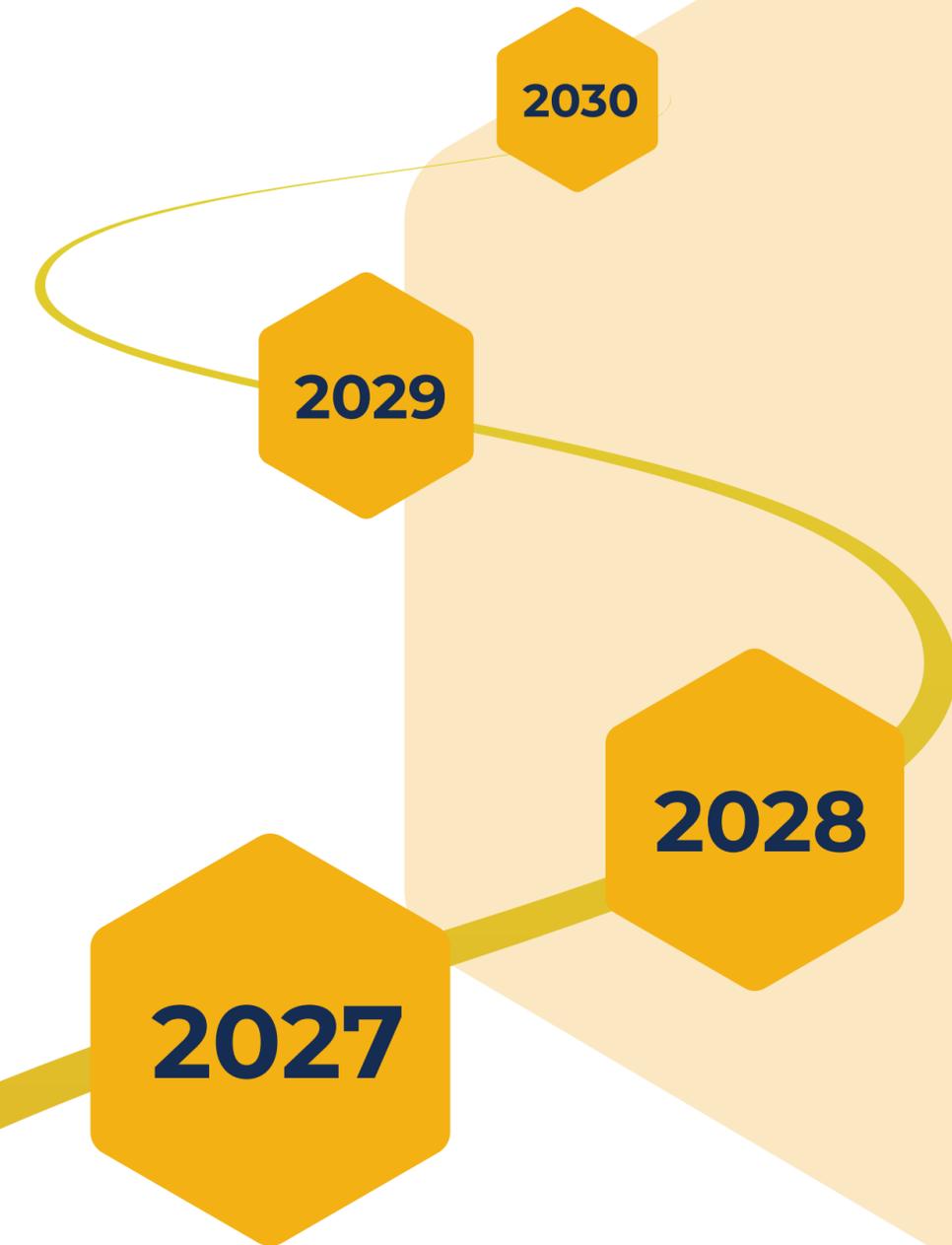
## STI multiplex kits

- CT-NG QL\*
  - Chlamydia trachomatis
  - Neisseria gonorrhoeae
- MG-MH-US QL\*
  - Mycoplasma genitalium
  - Mycoplasma hominis
  - Ureaplasma species (U. parvum, U. urealyticum without differentiation)

## Herpetic-viruses multiplex kits

- CMV-EBV-HHV6 QT\*
  - Cytomegalovirus
  - Epstein-Barr virus
  - Human Herpesvirus 6 A,B
- HSV1-HSV2-VZV QT\*
  - Herpes Simplex Virus Type 1
  - Herpes Simplex Virus Type 2
  - Varicella-Zoster Virus

\*QL = qualitative, QT = quantitative



# Positioning of PCR kit brands

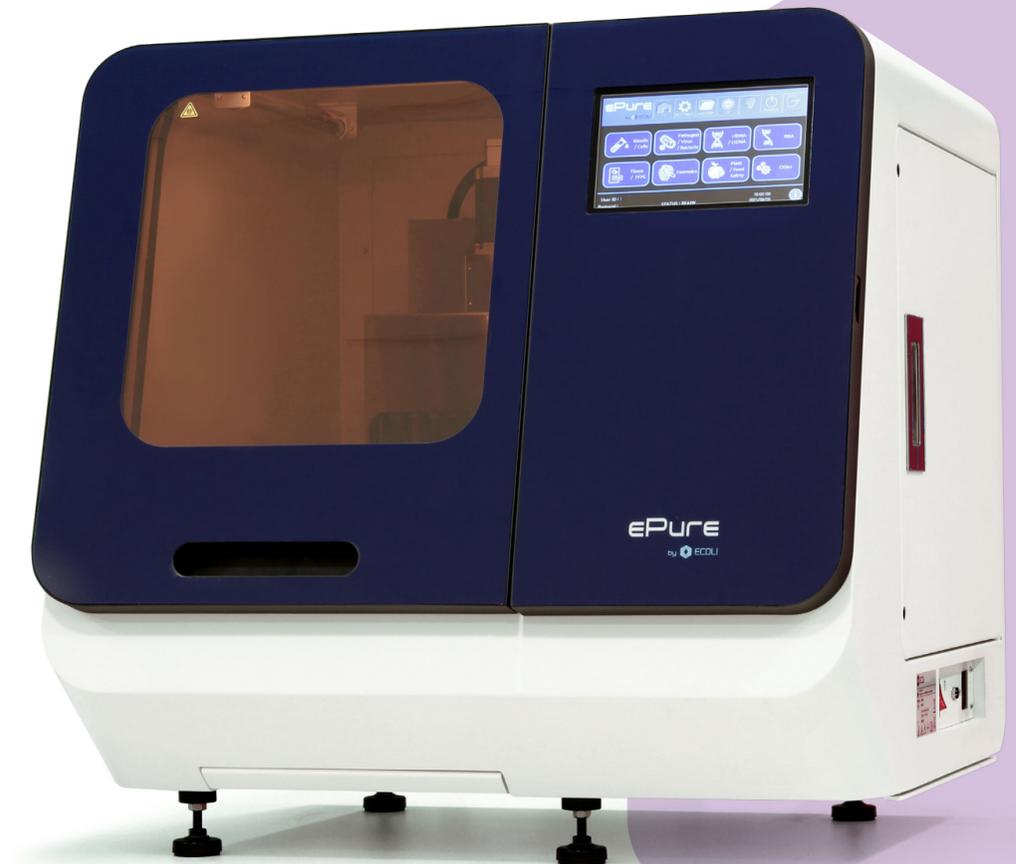
- Customers who are fine with **RUO**
    - AmpliSens**
    - eDetect RUO**
    - eSens** (group D according to IVDR criteria)
- 
- Customers requesting **CE IVD**
    - eSens:** legacy CE IVD-D
      - Decided to take steps to meet the IVD-R requirements for their continued marketing
    - eDetect:** CE IVD-R
      - Will be our main CE IVD solution along with the new instrumentation
      - Main focus from our distributors expected



# ePure

## Fully automated nucleic acid extractor

- Liquid handling instrument based on magnetic particle extraction technology
- Purifies 1 to 12 samples simultaneously per run
- Compact bench-top design
- Built-in UV lamp decontamination
- Optimized in-built protocols
- Range of purification kits that contains all prefilled reagents and consumables



# ePure extraction kit menu

Cat.No.	Product name	Size	Description	Availability
E2001	ePure Blood DNA Extraction Kit	48 tests	extraction of genomic DNA from whole blood, buffy coat and leukocyte concentration	✓
E2003	ePure Viral Nucleic Acid Extraction Kit	48 tests	extraction of viral DNA/RNA from serum, plasma or cell-free fluids	✓
E2004	ePure Tissue DNA Extraction Kit	48 tests	extraction of DNA from solid animal tissues, dried swab and dried blood	✓
E2006	ePure Bacterial DNA Extraction Kit	48 tests	extraction of bacterial DNA from various sample types including environment material	✓
E2007	ePure STD Extraction Kit	48 tests	extraction of nucleic acid from cervical swab and transfer medium	✓
E2008	ePure TB DNA Extraction Kit	48 tests	extraction of MTB DNA from various sample types (e.g. sputum, BAL, CSF, urine, blood)	on request
E2009	ePure FFPE DNA Extraction Kit	48 tests	extraction of genomic DNA from formalin-fixed, paraffin-embedded tissue (FFPE) samples	on request
E2010	ePure Forensic DNA Extraction Kit	48 tests	extraction of genomic DNA from a wide range of forensic & human identity samples	on request
E2014	ePure Plant DNA Extraction Kit	48 tests	extraction of genomic DNA from plant tissue and yeast	on request
E2015	ePure Total RNA Extraction Kit	48 tests	extraction of Total RNA from mammalian whole blood, human and animal tissues, cultured cells, plant tissue and yeast	on request



# eQuantix introduction

- **2 models**
  - Capacity **32** tubes – we have a prototype, **launch in 6 months**
  - Capacity **96** tubes – launch in 15 months
- **New technology of sample temperature ramp rate**
  - Shortens run time roughly by 30 %
- **High power LED**, Detector: CMOS
- **5-channels:** FAM/SYBR Green, HEX/JOE, ROX/TxR, Cy5, Cy5.5
- Laptop-like **silent** operation
- **Open platform** for any plastics/commercial kits
- **Own user-friendly SW**



# R&D projects overview

## eDetect

- 2 applied for CE IVD-R certification
- 3 in later stage of development
- 45 CE IVD marked kits by 2029

## eQuantix

- 32-tube version in 6 months
- 96-tube version in 15 months

## Sample-To-Result Platform Gen1

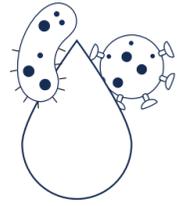
- OEM, similar technology to ePure, in 12 months

## Sample-To-Result Platform Gen2

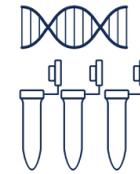
- Integration of  
our own extraction technology  
eQuantix technology
- In development



# Complete solution for PCR diagnostics of infectious diseases from A to Z

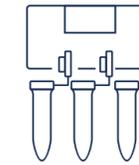


 AmpliSens®



 EPure

 AmpliSens®

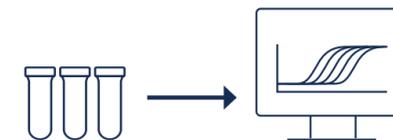


 EDetect

 EQuantix

 ESens

 AmpliSens®



# Support of our distributors

## Scientific & Technical Support

- **Helpful tech-support team**
- **Trainings**  
Application and service/hardware  
Online or at our facility near Prague
- Extensive resources on our web

## Regulatory & Documentation Assistance

- Helpful sales & regulatory team
- Extensive resources on our web

## Logistic & Operational Support

- Reliable order and shipping processing
- Support with import/customs documentation

## Business Development Support

- Joint participation in exhibitions or conferences
- Lead sharing (inquiries from your territory)



...AND PROVIDING  
COMPETITIVE  
PORTFOLIO

# 3 points of contact

## Logistics

- **[ecolidx@ecolidx.com](mailto:ecolidx@ecolidx.com)**  
For orders and requests for availability, delivery terms and shipping, product documentation

## Technical and service support

- **[techsupport@ecolidx.com](mailto:techsupport@ecolidx.com)**  
Pre-sale and post-sale technical questions on products, application support, technical claims with regard to PCR and extraction kits, hardware issues
- **[service@ecolidx.com](mailto:service@ecolidx.com)**  
Specifically for instruments, hardware/software issues and claims

## Sales

- **[tomas.vydareny@ecolidx.com](mailto:tomas.vydareny@ecolidx.com)**  
Anything that helps you grow  
Requests for special pricing, product registrations, trainings, contracts, authorization letters, events  
Business planning





**WE INVITE  
YOU TO  
VISIT US**



**ECOLI**

