



European Diagnostic Manufacturers Association

EDMS

European Diagnostic Market Statistics

For reagents & instrument sales

GUIDELINES

Version 2007
Market Research Committee

January 2008

IVD Sales Reporting according to EDMA classification

1. Objective

- To provide a comprehensive and continuing estimate of the In Vitro Diagnostic Market in your country based on an independent audit of invoiced sales.
- This sales audit is based on the invoiced sales for IVD medical devices and services in your country.

2. EDMA classification

- Your invoiced sales (sales generated in your country) should be reported according to the current EDMA Classification. This classification consist of the following **categories and groups**:
 - **1 Reagents**
 - 11 Clinical Chemistry,
 - 12 Immunochemistry (Immunology)
 - 13 Haematology/Histology/Cytology
 - 14 Microbiology (culture)
 - 15 Infectious Immunology
 - 16 Genetic testing
 - **2 Instruments and Consumables (related to instruments)**
 - 21 Chemistry / Immunochemistry instruments
 - 23 Haematology/Histology/Cytology instruments
 - 24 Microbiology (culture) instruments
 - 25 Infectious immunology instruments
 - 26 Nucleic acid testing instruments
 - 27 Micro-array instruments
 - 28 Sample processing systems
 - 29 Other instruments
 - **3 After sales**
 - 31 After sales services
 - 32 Spare parts (parts used by field service)
 - **4 Supporting software (bio-informatics)**
 - 41 Supporting software
 - **5 Sample container classification**
 - 51 Dedicated samples containers
 - **6 Total market (sum of 1-5) will be added up to a total sum.**

3. Method

Your net invoiced sales should be reported quarterly at parameter level. All reagents, controls, consumables and instrument devices as well as service have an independent EDMA classification code such as:

Examples:

- Clinical Chemistry: e.g. 11.02.01.31 Triglycerides
- PSA: e.g. 12.03.01.33 fPSA
- Haematology: e.g. 13.02.01.01 Prothrombin time



- HIV: e.g. 15 03 01 03 HIV Multiple Antibody
e.g. 15 03 20 09 HIV Multiple Ag/Ab Combi Test
e.g. 15 03 20 40 HIV Multiple-NA Reagents
e.g. 15 70 03 90 HIV 1/2 – Rapid Test

Special products and technologies with a dedicated intended use and features are identified with a special classification code number:

- 30: multi-parameter test, e.g. 12 06 **30** Multiple – Individual and Specified Hormones
- 40: nucleic acid test, e.g. 15.03.01.**40** HIV 1 – NA reagents
- 50: calibrators and controls e.g. 12.**50**.01.03 Hormone standards /calibrators
- 70: rapid test, e.g. 11.**70**.01.02 Glucose Test Strips
- 90: others e.g. 13.01.01.**90** Other Reagents for Haematology Analyzer

Participating companies should e-mail to CIP, France the independent auditor selected by the national trade association:

- ⇒ on a **quarterly** basis
 - ⇒ their **national net invoiced sales** (to laboratories, decentralized sites, pharmaceutical companies and OTC diagnostics)
 - ⇒ of **each parameter** (analyte)
 - ⇒ in **local currency**.
 - ⇒ sales to other Diagnostic companies, other affiliates or exports should **not be included**.
- The reported invoiced sales remain completely **confidential** at all times. Confidentiality is ensured via coding, by using CIP as well as by special rules suppressing the reporting of aggregate data unless three or more companies contribute data.
 - All company input (electronic transfers and completed input forms) is compiled by CIP. The auditor distributes to each participating company its own input data plus the aggregated data for the parameters and higher levels of classification with at least three companies contributing.
 - Country consolidated sales at parameter level and the total sums are returned to the participating companies by CIP.

4. Definitions and rules

Definitions

Accessory:

optional part of an instrument improving its performance, reliability....

Auxiliary reagents:

product systematically or occasionally to perform a test but required to comply with the analytical performances of the test

Consumables:

products not involved in the reaction process but required to perform "in vitro diagnostic" testing to be used once or several times or to be regularly replaced by a lab operator

Product:

reagent, calibrator, control material, auxiliary reagent, instrument, accessory, software, services, dedicated containers for samples specially developed or required for IVD testing

Rapid test:

test specially developed to be performed on the sample without any preliminary preparation

Reagents:

products actively involved in the reaction process

Spare parts:

part of an instrument requiring a professional technician to replace or repair it

Rules

EDMA classification code: most of the routine tests are clearly identified according to their name, intended use and technology

Instruments: to be allocated according to their main activity

Invoiced sales: reported sales are in local currency by product level

Non IVD products: applied sciences, medical devices, generic products (PC, printer, battery), non-finished goods and promotional material should not be reported in EDMS.

Products without EDMA classification code should be reported in "others" (90) on group, sub-group or test level according to its clinical scope, method and intended use

5. Sales Reporting

- To facilitate the reporting, companies should **allocate all company specific product identification numbers** (product list numbers) to the corresponding EDMA Code for example.

Company Product DESCRIPTION	LIST No.	SIZ E	EDMA Code	EDMA DESCRIPTION
SPEC ALT REAG	01349	003	110101030	Alanine Amino-Transferase
GPT UV DGKC	05F67	001		
GPT UV DGKC	05F74	001		
AERO ALT	07D56	001		
ALC ALT	08D49	001		
SPEC ALK PHOS REAG	01329	003	110101050	Alkaline Phosphatase - Total
ALK PHOSPHATASE	05F66	001		
DGKC				
ALKPHOSPHATASE	05F73	001		
DGKC				
AERO ALK PHOS	07D55	001		
ALC ALK PHOS	08D48	001		

- Before sending the first sales data to CIP, new companies should request for an **identification number** (company code), which should be included on all sales data input forms. This company code will be allocated by CIP and remains confidential.

5.1. Sales reporting using the data input format

- Companies will receive from each participating National Association a copy of the **Data Input Form**. This should be held as a 'master copy' and each company should **make replicates** to use for the quarterly returns. The data input form will be sent by e-mail - **see separate file**.
- The **Data Input Form** is a spreadsheet in **EXCEL**
- The **preferred method** of reporting sales data to CIP is centrally from the company headquarters responsible for Europe. Companies are encouraged to contact CIP to arrange details. Centrally reporting companies should also send data for all European countries whose national associations are not yet participating.
- The headline of the sales report **must** be completed by the participating company, correspondingly, such as:

- ⇒ Company code
- ⇒ Country
- ⇒ Period
- ⇒ Currency unit

e.g.

EDMS - European Diagnostic Market Statistics - Data Input			
Form			
Company code:	XX	Period:	1Q/06
Country:	DE for Germany	Currency unit:	Euro 000'

Completing the Data Input Form

- The Data Input Form consists of five columns.

-

EDMA CLASSIF.			CIP CODE	TOTAL Sales in local currency Please insert here!
10	REAGENTS			
11	CLINICAL CHEMISTRY			
11.01	Enzymes			
11.01.01.0 1	5'-Nucleotidase	NTP	1846	15500
11.01.01.0 2	Acid Phosphatase (CC) IC => 12.03.90.13	ACP	1717	1033

Column 1 is the EDMA Classification code
 Column 2 lists the parameter names
 Column 3 is a parameter abbreviation
 Column 4 is the CIP code
 All four columns are protected
 Column 5 (COLUMN A) is for entry of data

- The Subtotals and Totals will be calculated automatically by CIP and no sales should be reported in any total or sub-total lines.

5.2. Sales reporting via download

- You can also send the company sales data in an Excel format. The table needs to consist of the following data and should be in this distinct follow up:

Country	Company	Year	Period	Currency	SALES	EDMA Code				
					EURO					
DE	XX	2005	Q4	EUR	162033	11	01	01	03	00
DE	XX	2005	Q4	EUR	71721	11	01	01	05	00
DE	XX	2005	Q4	EUR	190352	11	01	01	07	00

- The file name should be named as following:
 company code_country_Q4_2005.xls e.g.
 XX_DE_Q4_2005.xls
- Quarterly sales are reported as Q1, Q2, Q3, Q4_2006
- The Subtotals and Totals will be calculated automatically by CIP and no sales should be reported for total or sub-totals.
- ISO country code abbreviations at the end of this document.

5.3. CIP, France (Independent auditor) Contact Details

- **E-mail to: gilles.dubroeuqc@cipclub.org**

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c/o GILLES DUBROEUCQ
Tour Franklin 22nd Floor
100-101 Quartier Boieldieu
92042 PARIS La Défense Cedex / France**

**Tel: +33 1 70 36 03 11
Fax: +33 1 70 36 03 01
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6. Sales Statistics Output

The consolidated national sales statistics by CIP will provide (see attached file – EDMA report_example):

- Total sales turnover of the individual* company versus the total** of all reporting companies for each
 - ⇒ Parameter
 - ⇒ Subgroup
 - ⇒ Group
 - ⇒ Category
- by
 - ⇒ Quarter
 - ⇒ Year to date (accumulated quarters) = YTD
 - ⇒ Moving annual total (4 last quarters) for current and previous period = MAT
- Variance (+/- %) over the same period previous year of own company and all companies
- Market share in % and rank order (#) of own company (quarterly and MAT)
- Number of participating companies per product line (EDMA code) for actual quarter and MAT
- A list of all companies reporting sales of the parameter in the rank order of market share for the current quarter and MAT versus the previous year
- Electronic file (including sales of the 9 last quarters) for use with CIP databank – Matrice_Diags – available from CIP – special user guide (see page 8 – User guide Matrix)

* Individual company figures are reported only to the company concerned.

** Consolidated sales are only reported when 3 or more companies in the same product line.

From CIP you will receive a zip file called Reagents_XXX.ZIP - this file consists of 2 files: The file DZ XXX.CSV is the actual consolidated statistics which you open in the Matrice data tool.



The second file called LZ XXX.CSV is the file where all companies reported in the statistics and the corresponding abbreviations are stated. With a double click the file opens.

Please contact by any question:

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ISO country names abbreviation codes:

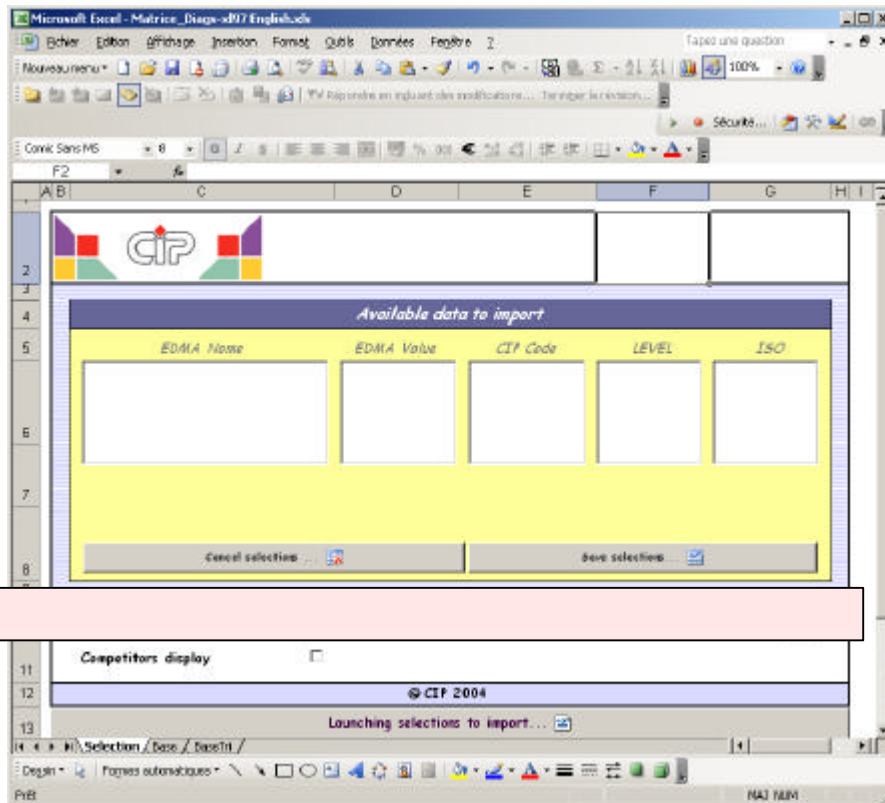
Country name	codes
Austria	AT
Belgium	BE
Bulgaria	BG
Croatia	HR
Czech Republic	CZ
Denmark	DK
Estonia	EE
Finland	FI
France	FR
Germany	DE
Greece	GR
Ireland	IE
Italy	IT
Latvia	LV
Lithuania	LT
Macedonia (former Yugoslavia)	MK
Monaco	MC
Netherlands	NL
Norway	NO
Poland	PL
Portugal	PT
Romania	RO
Russian Federation	RU
Slovakia	SK
Slovenia	SI
Spain	ES
Sweden	SE
Switzerland	CH
Ukraine	UA
United Kingdom	GB



EDMA SURVEY OF SALES STATISTICS (EDMS)

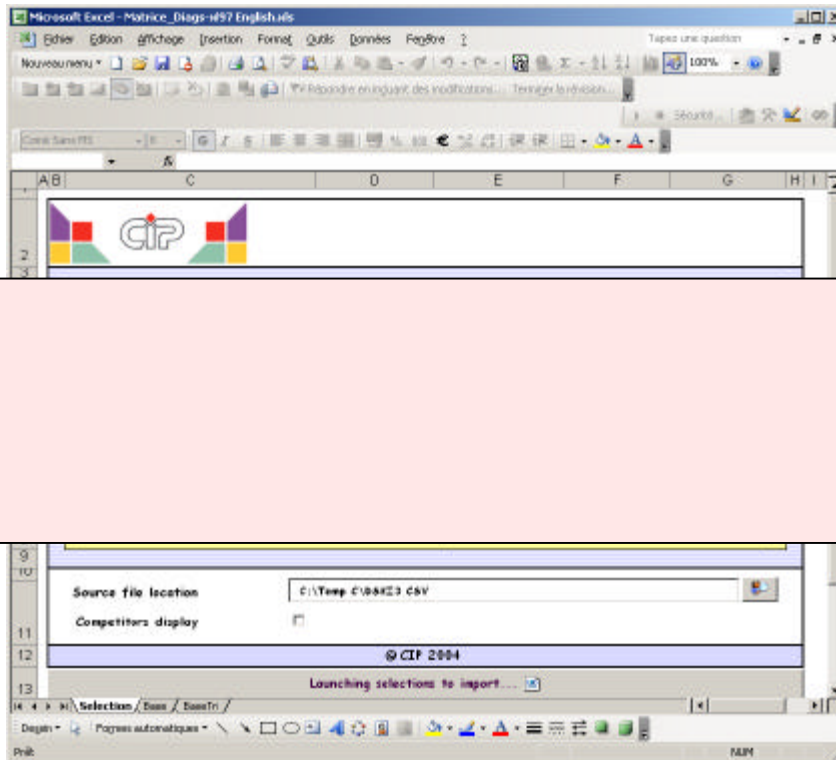
CIP Consolidated Report – Matrix Instructions

- In the Matrice_Diags file macros are included. First open file and enable the macros!
 -
 - The first page of the matrix tool opens:
The databank consists of 4 Excel sheets, which should never be deleted:
 - 1) «Selection» sheet: Selection of the data in the sheet «results».
 - 2) «Base» sheet: used to generate the sheet «results».
 - 3) «BaseQuarter»: used to generate selections backup.
 - 4) «BaseTree»: EDMA classification.
1. Data source file location used for data processing:
- **File dsk XX.csv zipped in reagents.zip ».**
 - **Unzip the file and store it in your statistics folder – please use only data files with .csv ending! Do not open this file in another tool before hand.**
 - **Go to line < Source file location> and load your actual csv file out of the folder.**



- Selection of the « .CSV » file will import all the data into the matrix, allowing the selection of data in results report.

2. Data Queries:



2

- **Data query can be made based on 3 criteria:**

- 1) *EDMA Code (Name for product) or EDMA Code (Value) or CIP Code*
- 2) *LEVEL*
- 3) *ISO – relevant only for Germany*

Selection process is typically « Windows »:

- To select one item in the list, click once on this item.

- To select several not contiguous items, keep prop

- « Ctrl key »  of the keyboard while selecting of the product or code

- To select several contiguous items, click on the first item, keep

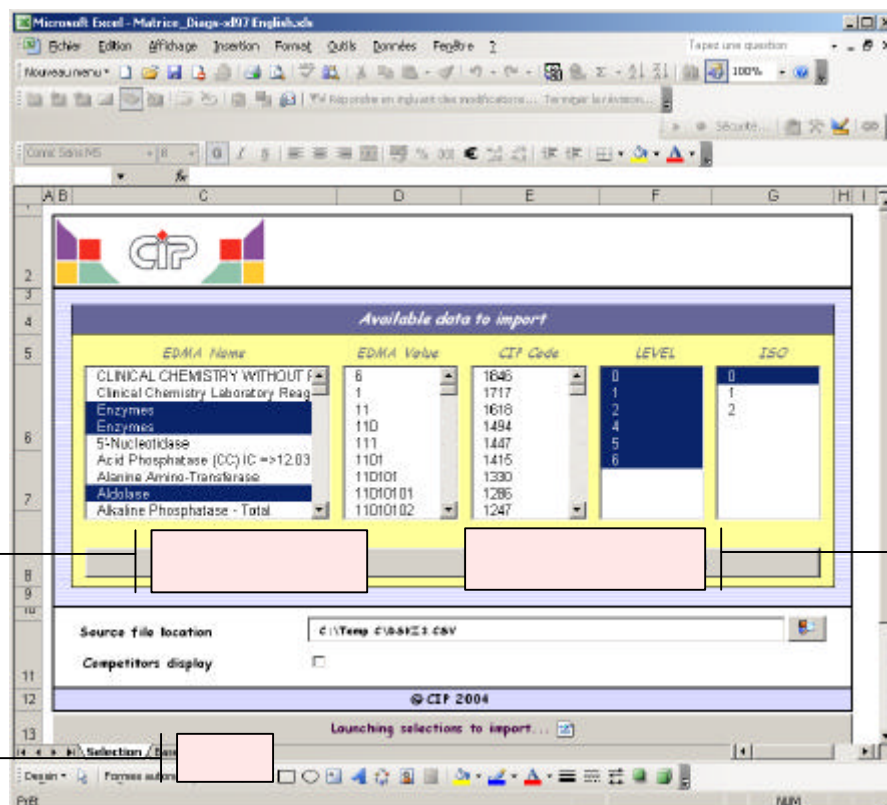
prop « Shift key »  of the keyboard and then select the last line to take in account.

Note:

If any selection is made in a list when launching importation, the interface will select the whole item list.

Example: the first criteria consist of 3 items, then «EDMA Product (name) and «EDMA Code (value) cannot be selected simultaneously.

Prior to selecting a new query such as EDMA code (value) after the utilization of EDMA product name or vice versus you need to cancel the previous selection with the button « Cancel selections »



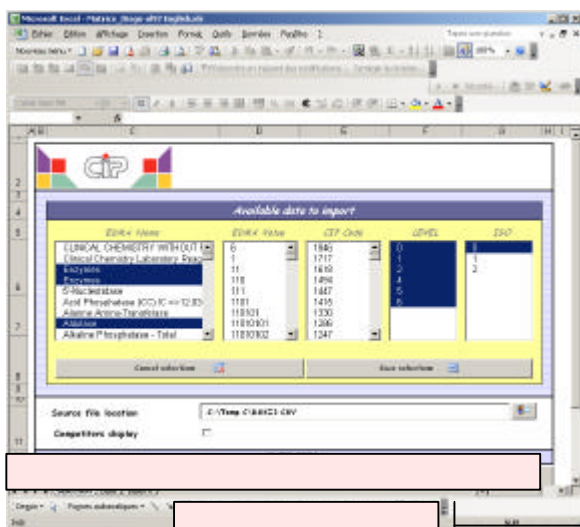
A back up of the current selection is made by a click on the button « Save selections »

This back up is generated when importing criteria .The sheet made by this processing is named « BaseTri ». All the selections are included.

During the following back up, this sheet will be copied with the new selections.

!! IMPORTANT / don't delete « Base Tri» sheet, back up sheets are updated with each new query.

3. Result sheet:



- The result of the selected query is generated with the button <Launching selection to import>.

- Tic this button when results should be generated with competitor lists.
- A second button is inserted in this line - Tic when the last 9 quarters of an item is queried.

